Negotiating Research Participation in Community-Based Studies on the Kenyan Coast: Fieldworkers' Roles, and Implications for Ethical Practice

Thesis

Negotiating Research Participation in Community-based Studies on the Kenyan Coast: Fieldworkers' Roles, and Implications for Ethical Practice

Dorcas Mwikali Kamuya
Bsc (Agric. Econ.), MPH

A thesis submitted to the Open University,
Economics Discipline,
in part fulfilment of the Degree of
Doctor of Philosophy

Sponsoring Establishment
Kenya Medical Research Institute-Wellcome Trust
Research Programme, Kilifi, Kenya.

October 2012

DATE OF SUBMISSION : 30 OCTOBER 2012
DATE of AWARD : 20 APRIL 2013

Abstract

In this thesis, I explore the nature of research interactions between fieldworkers (FWs) and research participants in a large, long-term international collaborative centre on the Kenyan Coast. Fieldworkers are members of local communities employed in research with the main responsibilities of communicating about studies, and carrying out biomedically simple, non-invasive procedures. Being socially embedded in the communities in which research is conducted, fieldworkers can potentially strengthen studies and research ethics through their insider knowledge of local norms, and of hard-to-reach populations. Being socially embedded can also present problems on how to respond to questions and demands in a context of wealth and health inequalities. I designed a mixed methodology study, primarily qualitative, to unpack the issues that fieldworkers at the frontline of research implementation face, how they resolve these, and the implications for policy and practice.

I found that fieldworkers and other research staff working in communities face considerable dilemmas including those related to household decision-making dynamics for research; and those related to types, levels and scope of research benefits given to participants and communities. The nature of pre-existing relationships within households, and of relationships developed between FWs and household members, apparently strongly influenced discussions and research participation choices. Relationships were often built and nurtured by both fieldworkers and participants. 'Silent refusals'- a situation of inconsistent participation and reluctance to openly refuse or withdraw from research - emerged as a key challenge for fieldworkers. Negotiations were often imbued with subtle power relations across different sets of

interactions; within households, between FWs and participants, and between FWs and supervisors, with potential to shift and shape the research implementation processes. There were often no easy answers to these and other issues fieldworkers faced; they appeared to draw on study guidelines, formal and informal supervision, peers and their own judgements in making choices.

Drawing on these findings, I suggest that understanding and responding to the issues that fieldworkers face throughout their fieldwork is important in supporting the practical application of ethics guidelines including those related to community engagement and consent; and in contributing to normative debates.

Acknowledgement

This research was funded through the KEMRI Wellcome Trust's Strategic Award. Part of my writing phase was funded through a grant from the Ethox Centre, university of Oxford. Many people contributed in one way or another to the conceptualization of this research and to seeing it to its completion. I am deeply grateful.

I am especially grateful to my supervisors, Dr. Sassy Molyneux, Dr. Sally Theobald and Dr. Paul Wenzel Geissler for their tireless efforts in supporting my research, mentorship, for challenging me to think in new ways and for nurturing my intellectual curiosity. Special thanks to Dr. Sassy Molyneux for supporting me throughout this journey; Dr. Sally Theobald for providing a home at the International Health Group at Liverpool school of Tropical Medicine (LSTM), Faye Moody for sorting out my accommodation and my stay at LSTM; and colleagues at LSTM, for intellectually stimulating conversations.

My deep appreciation to Prof. Mike Parker, Ethox Centre, University of Oxford, for your interest in my research and for making this research journey seem tireless.

I am grateful to Dr. Karina, for going through my initial transcripts and working together to develop the initial thematic framework; the oversight provided by the Student Advisory Committee (SAC), Dr. Charles Mbogo, Dr. Catherine Goodman and Prof. Thomas William. Special thanks to the Upgrading Committee, which consisted of the SAC members and Prof. Kevin Marsh, Dr. Jane Chuma and Prof. James Nokes, for your critical insights that helped shape this research.

This work would not have been possible without the support of the fieldworkers at the research centre. Special thanks to the fieldworkers and participants in the two case studies for the numerous conversations we had throughout this research and for welcoming me into your circles. I am grateful to the Principal Investigators (PIs) and researchers in the two case studies; Patrick Munywoki, Dr. Patricia Njunguna, Dr.

Roma Chilengi, Prof. James Nokes, Charity Maingi, Dorothy Koech; and the senior FWs.

My colleagues in the Health Systems and Social science Research (HSSR) and the Community Liaison Group (CLG), you provided a foundation for this research, our discussions, both work-related and informal enriched it in many ways. I am grateful to the community liaison group members; Salim, Kombe, Hassan, Masha, Rimba, Anderson, Isaac, Gladys, Jane, Betty, Dorothy, Metrine, Wilma, Kanini. I enjoyed working with you. I especially want to thank interviewers/enumerators and translators for this research, Gladys, Anderson, Isaac, Jane; and our data entry staff; Metrine, Kanini and Wilma. Thank you, Maureen Njue for diligently working many hours during the household survey; Vibian and Judy for support during the household survey and case study work.

I am especially grateful to Dr. Vicki Marsh, for your unwavering support, for your insights and for encouraging this dream to become a reality. Dr. Doris Kirigia for putting up with my constant enquiries, and knowing when it was time for a coffee break; Dr. Jane Chuma, for setting a vision for many of us to emulate, Alun Davies, for the many debates we had; and Dr. Caroline Jones for your oversight.

The training department at KEMRI-WT, for providing a hub in which I could explore my ideas, thanks to Dr. Sam Kinyanjui, Liz Murabu, Prof. James Nokes among others. I am deeply grateful to Symon, Julie, and Dr. Greg Fegan for statistical advice. To Nyundo, Onesmus, and Dr. Bauni, thank you for providing maps promptly when we need them. Much appreciation to the ICT department, Anne, Lucas, Ralph, Eduard, Prisca, for sorting out all computer related issues; the Human Resource Department, Kathleen, Jefwa and Hillary for putting up with my constant enquiries; and the transport department, Elijah, Kalachu, and the team of drivers, for ensuring my field work went on uninterrupted.

Paulina Tindana, my sister from Ghana, you have been my rock, champion and friend throughout this journey. We had many intellectually stimulating conversations, of dreams of research in Africa. I am eternally grateful to you and your family for hosting

me in many ways when I visited Oxford. Tracey Chantler and Dinnah Digecho in Oxford and Jantina Devries in South Africa, thank you for supporting me in this work. To many others I interacted with in this journey: Ernest, John, Edward, Tamzin, Trudie, Angeliki, Patricia, Susan, Andrew, Aisha, Ganle, Lairumbi and my friends who kept me grounded, Tabs, Editta, Betty, Sarah, Tsofa, Kalachu, Neema, Edna, Kelly, Martha and many others *Asanteni Sana.*

I am especially grateful to my family; my dad, brothers, sisters, nephews, nieces and my extended family, for understanding and patience when I needed these most, and for always including me in your prayers. Thanks to Mary, who is like a sister, for making sure there was a hot plate of food at home. My sister Stella, we have walked this journey together in many ways. My final word of gratitude is to my mum, I wish you could have seen the fruition of this journey

.

Dedication

To my late Mum, Phoebe Kakwasi Kamuya (1940-2012). Mum, you were my mentor, my confidant, and my friend. You always cheered me on, encouraged me when I was unsure, saw possibilities when I saw none. You taught me to always strive for fairness and justice, and to put God first in everything. You so looked forward to my submitting this thesis and I know you are watching and cheering me on. I will always miss you *mwaitu*. May you rest in Peace.

Table of contents

List of Tables

List of Figures

List of Photos

Appendices

Abbreviations in main text

CABS	Community Advisory Boards
CAST	Communication Advice for Specific Study Teams
CBA	Community-Based Assistant
CBO	Community Based Organization
CCC	Consent and Communication Committee
CDC/ATSDR	Center for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry
CE	Community Engagement
CF	Community Facilitator
CFR	Code of Federal Regulations
CHW	Community Health Worker
CIOMS	Council for International Organizations of Medical Sciences
CLG	Community Liaison Group
CLM	Community Liaison Manager
CORP	Community Own Resource Person
CSA	Case study A
CSB	Case study B
CSW	Commercial Sex Worker
DC	District Commissioner
DHMB	District Health Management Board
DHMT	District Health Management Team
DO	Divisional Officer
DPT	Diphtheria, Pertussis, Tetanus: A combination vaccines against three infectious diseases.
DSMB	Data Safety Monitoring Board
ERC	Ethical Review Committee
EZ	Enumeration Zone
FA	Field Assistant
FDA	Food and Drugs Association
FGD	Focus Group Discussion

FW	Fieldworker
GCP	Good Clinical Practice
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
IDI	In-depth Interview
IDU	Intravenous Drug Use
KCR	KEMRI-Community representatives
KDH	Kilifi District Hospital
KEMRI-	Kenya Medical Research Institute
CGMRC	Centre for Geographic Medicine Research, Coast
WT(RP)	Wellcome Trust (Research Programme)
KHDHSS	Kilifi Health and Demographic Surveillance System
Kms	Kilometres
KNBS	Kenya National Bureau of Statistics
Ksh.	Kenya Shillings
MOH	Ministry of Health
MoMS	Ministry of Medical Services
MoPHS	Ministry of Public Health
MRC	Medical Research Council
MSM	Men who have Sex with Men
NCAPD	National Coordinating Agency for Population and Development
NCST	National Council of Science and Technology
NFS	Nasopharyngeal Flocked Swab
NG	Natural Group
NIH	National Institute of Health
OF	Oral Flock swab
Pax	Participant
PATH	Program for Appropriate Technology in Health
PCD	Passive Case Detection
PDR	Peer Driven Sampling
PHS	Protection of Human Subjects
PI	Principle Investigator

RA	Research Assistant
RDS	Respondent Driven sampling
RSV	Respiratory Synctial Virus
RTSS/ASO1E	A candidate malaria vaccine;
SA	South Africa
SAE	Serious Adverse Events
SCC	Scientific Coordinating Committee
SDA	Seventh Day Adventist
SFW	Senior Fieldworker
SOP	Standard Operating Procedure
SR	Silent Refusal
SSA	Sub-Saharan African
SSC	Scientific Steering Committee
USA	United States of America
USD ($)	US Dollar
WHO	World Health Organization
WMA	World Medical Association

Abbreviations used in interview quotes

Pax	Participants
R	Researcher
CF	Community facilitator
FW	Fieldworker
SFW	Senior Fieldworker
CSA	Case study A
CSB	Case study B
CLG	Community Liaison Group

System of allocating participant numbers

Interview description	Numbering of interviews	Example
Community Liaison group (CLG) Field workers (FWs) and Community facilitators (CF)	FGD01-FGD04	FW3, female, CLG/FGD03 CF1, male, CLG/FGD01
FGD with RSV FWs (3FGD)	FGD05–FGD07	FW4, male, CSA/FGD05
FGD with RTSS (CSB) FWs - 3 FGDs	FGD08-FGD11	FW9, female, CSB/FGD09
FGD with RTSS SFWs (1 FGD)	FGD11	SFW4, male, CSB/FGD11
Natural (household) group discussions with case study A participants (5 discussions)	HH1 – HH5	Pax1, male, CSB/HH01
FGDs with participants in case study B (4 FGDs)	FGD12–FGD15	Pax7, female, CSB/FGD11
Two IDI with RSV study PI	IDI01 and IDI04	R1, male, CSA/IDI01
Two IDI with RSV study coordinator	IDI02 and IDI05	R2, female male, CSA/IDI02
IDI with RSV SFW	IDI03	SFW, male, CSA/IDI02
IDI with RTSS best performing FW	IDI07	FW, male CSB/ODI07

Translation of Swahili words

Baraza	Public meeting usually organized by the government administrator (chief)
Daktari	Doctor
Fidia	Compensation
Giriama	One of the nine sub-tribes forming the larger Mijikenda tribe, the indigenous tribes of Coastal Kenya
Huduma	Services
Majaribio	Trial
Makuti	Coconut leaves used for thatching houses, common in the Coast region
Malu	The compensation for adultery with a man's wife or daughter
Mijikenda	Literally means 'nine homes' or 'nine homesteads' (in Swahili), pointing to the common ancestry of the nine sub-tribes in Coast: Chonyi, Duruma, Digo Giriama, Jibana, Kambe, Kauma, Rabai, and Ribe.
Miyani	Likened to vampires and blood sucking (see White 2000). In the rumours it was claimed that young men were employed in research and by the medical profession to drain blood from unsuspecting villagers, which was then sold
Mnazi	An alcoholic drink made from tapping coconut juice.
Nyanjani	In the field or in rural areas
Pata potea	A local game similar to dice game with animals instead of numbers. If the chosen face of anima lands face down, the player looses.
Uchunguzi	Investigate for treatment but also sometimes used to refer to research.
Uhusiano	Cooperation, or working together collaborative, also used to mean good relationship.
Unaweka kiba	Investing.
Upendeleo	Favouritism or nepotism
Utafiti	Refers to research, but also to standard diagnostic investigations

Glossary of key terms

Key term	Definition
Fieldworkers (FW) (Simon and Mosavel 2010)	General: Community members involved in assisting with research activities, also called Community Research Workers (CRWs); involved in recruitment of participants, including from their social networks or in hidden populations. Includes such groups as peer recruiters and village reporter; Research-specific: community members with a minimum of 12 years of schooling, employed as staff at the KEMRI-WT research centre. Their main roles include communicating about studies, undertaking consent processes, and performing biomedically simple non-invasive procedures;
Community (Lavery, Grady et al. 2007; Ragin, Ricci et al. 2008)	General: Contested definition; refer to a group of people with a commonness e.g. residence, religion, race, profession; membership can be by choice, or based on innate personal characteristics (e.g. kinship, social-demographic characteristics). It can also be internally defined by members of the community themselves or externally defined by researchers; Research-specific: One important 'community' in this thesis refers to the nearly 260,000 residents of a geographically defined area, who are followed-up three times a year as part of the Kilifi Health Demographic Surveillance System (KHDSS); For case study B, which was outside the KHDSS, community refers to residents of the geographic locality where the study was conducted; In the thesis, I have tried to clarify which of the two 'communities' are referred to;

Community engagement (CE) (CDC/ATSDR 1997; Green and Mercer 2001)	General: In its broadest sense, community engagement implies some form of interactivity between researchers and study communities. The depth of CE can range from simple information giving, through active consultation, to higher levels of partnership characterized by joint decision-making, power-sharing and equitable involvement of stakeholders in a study; Research-specific: All forms of CE as defined above;
Principlism/ ethical principles	General: A systems of ethics guiding research based on the four moral principles of autonomy (agency or free will), beneficence (to do good, benefits to outweigh risks), justice (fairness in distribution of benefits and burdens) and non-maleficence (do no harm). Provides guidance on research conduct and researchers responsibility to those invoked in research (participants, communities); Research-specific: Adopted the above definition;
Social relations (Bajos and Marquet 2000)	General: The connections or structures that shape the nature of relations between groups or individuals; e.g. belonging to a group, gender, generation, social; Research-specific: Relationships formed during conduct of research;
Relational ethics (Evans, Bergum et al. 2004)	General: Based on the principle that people intrinsically care about each other, and focuses on relationships as the centre of ethical interest (Ellis 2007). In health care, Bergum at el (2004) describe relational ethics as a third entity between interacting persons, a relational space that requires attention and nurturing; Research-specific: Research participation provides social space

for nurturing relationships. The nature of the relationships can potentially influence responsibilities of those involved. Recognises relationships as bounded in interactions between FWs and research participants in ways that can be facilitative of ethical research conduct; and can also be ethically challenging;

Chantall[1] *is a 21 year old form four school leaver who joined Kenya Medical Research Institute - Wellcome Trust Research Programme (KEMRI-WT) in 2010 as a fieldworker (FW), two years after she completed her secondary school education. She had hoped to join a public (Government) university and was disappointed when she did not meet the minimum entry points.*

Chantall's father died while she was in her sixth year of primary school. She is the first born of six siblings, the rest being at various levels of education. Two of her siblings are now in secondary school and require fees to be paid to stay in school. She worries that if they regularly miss school due to lack of fees they will also perform poorly in national examinations and fail to get into university. Her mother has single-handedly educated all of her children with the little income she earns through casual labour on neighbouring farms, and with assistance from various government offices and well-wishers. However, the funds are never enough to keep the children in school all of the time.

Chantall said she is used to hardships in life. They often slept without food; waiting for government rations which were in any case inadequate for the family. They were known in the village as the poor family that always begged for help, which she loathed. Before being employed by KEMRI-WT, she thought of joining the 'street business' (commercial sex work), but knew that her mum would never allow it. She also did not want to be a disappointment to her family. After her father's death, his family allowed them to live in the extended homestead, but they were expected to contribute to the household budget, which sometimes strained homestead relations. Chantall had to take a loan from a neighbour to clear an outstanding fees bill in order to get her examination result slip, with which she could seek formal employment.

Chantall knows that her mother is looking to her to help in educating the rest of her siblings and pay some bills. While she was afraid of joining KEMRI-WT because of its' rumoured association with devil worship, she had no other job offers. Her pastor and church prayed for her, and she believes her faith would protect her against any evil. She talked positively of the initial training by the Community Liaison Group (CLG) at KEMRI-WT in addressing her initial fears, and watches keenly what goes on in the research centre. So far, she thinks that the stories are just rumours.

Chantall says that her mum is very happy that she is helping with the bills; she has paid a school fees debt for one sibling with her new income, and is paying off her loan. She hardly has any money left to spend on herself, but is relieved to be helping her family. She worries about the future should her KEMRI-WT contract be terminated or not extended. So a simple mistake or reprimand from her superiors, however slight, keeps her awake at night. The friendship she has cultivated with the participants is apparently very important to her; she feels that she is giving something back to the community that helped her family so much.

[1] Names used are not the real name of the people referred to in this vignette, and the photo does not represent the person described in the vignette.

CHAPTER 1 Introduction and overview of the thesis

1.1 Introduction

This thesis is about fieldworkers, a cadre of staff employed in research activities at KEMRI-Wellome Trust Research Programme (KEMRI-WT). In this study, I explored the nature of research-related interactions between FWs and research participants, and how these influenced research participation. At KEMRI-WT, a long-standing international collaborative research programme on the Kenyan Coast, FWs are community members with at last 12 years of schooling employed in research activities. The nature of their roles, of communicating study information, undertaking consent processes, and carrying out biomedically simple non-invasive study procedures, mean that FWs are constantly interpreting study protocols in their daily work. The very reasons for employing FWs in research activities, including their ability to provide insider knowledge about the community to researchers, and to negotiate cultural and local sensitivities of the research, can also present practical and ethical challenges and dilemmas for FWs, and for studies. FW roles are not just about following the neat descriptions of professional conduct as outlined in standard operating procedures (SOPs) and ethics documents, but also about making judgements and choices when they are faced with challenges. Their roles, where these involve consenting processes and collecting of research data, are important for ethical practice, and for scientific validity and credibility of studies.

1.2 My research journey: searching for meaning

> "...all researchers will have a particular world view, or theoretical perspective, which both underpins and shapes their project and findings" (Green and Thorogood 2007 p8)

My research journey has been informed by my experiences, past and present, at the interface between the institutions I was, and I am, employed by, and the clients, often community members, I have been employed to work with. My early years of employment after undergraduate training were as an agricultural practitioner employed by the Government to head a district departmental office in Kilifi. My role included negotiating ministerial policies at the district level, a role that was often complicated by top-down planning, limited resources, and huge workloads. There were also high expectations of me from both the employer and the community members I worked with. In my next stint, in community development, I nurtured a passion for community-driven approaches, not because it was easier, but because the voices that the development was intended to benefit were heard, and their priorities were taken seriously.

Joining KEMRI-WT nearly seven years ago allowed me to draw on my previous experiences in an enriching and challenging way. It has been enriching in that, with a group of social science researchers at KEMRI-WT, we have been working through uncharted pathways (for us) to engage meaningfully with different types of communities in biomedical research - a discipline that is often knowledge-driven and researcher-led. Interfacing between the researchers, the research organization and community members has required incredible negotiation skills; skills I learned early in

my life as a middle child of a large family living in rural Kenya. As part of my roles at KEMRI-WT, I have frequently interacted with scientific staff, trained different cadres of staff including FWs and FW supervisors, and handled issues[2] from the community. My initial research interest was around evaluating the KEMRI-WT community engagement strategy. However, during my early exploration of the research topic, it became evident that FWs were doing a significant amount of community engagement, which was not always formally recognised. Even though their roles are central in ensuring that scientific data are accurate and research conduct is ethical, there was relatively little empirical research about how FWs conduct their roles in the community. As discussed in 2.5, contributing to filling this gap became my central interest.

1.3 Theoretical framing of this research

I draw on two bodies of theories to shape and inform this research; the principles paradigm of research ethics with a focus on respect for persons and communities; and social relations theories with a focus on relational ethics.

The extent to which ethics principles are universal is contested, and particularly the extent to which individual autonomy, under the ethics principle of respect for persons, is prioritised or attainable across different contexts. Respect for persons, it can be argued, encapsulates relational notions of the responsibilities of researchers towards participants, and a recognition of the power differentials between researchers and participants (Lavery, Grady et al. 2007). The ethical framework for shared understanding in consent processes recognises the inherent interaction and discussions

[2] I use the word 'issues' in this thesis to refer to a problematic situation or an area that is contested.

between potential participants and researchers (or those undertaking informed consent) (Lindegger, Milford et al. 2006). Negotiation, defined as a discussion that aims at reaching an agreement, is inevitable in consent processes. This is arguably especially the case in populations where narrative (face-to-face) forms of communication are more central (Sin 2005), as is the case for many populations in developing countries. The spectrum of negotiation can range from simple information sharing to processes aimed at influencing choices. The latter is problematic in research conduct because of potential to undermine an individual's autonomous choice (Sanchez, Salazar et al. 2001). The focus in this research is on negotiations between a potential participant and research staff or significant others, often in the context of unequal power relations.

Despite the relational nature of consent processes, and of research participation, the implications of relational ethics for research decision-making have received relatively little attention (Sin 2005; Gikonyo, Bejon et al. 2008). In some instances, relational aspects of consent are treated simply as 'background noise' with potential to mire the assumed objectivity of the consent process. This is especially the case where the legal framework for consent, as opposed to moral commitment, has assumed primacy (Lindegger, Milford et al. 2006). Developing country contexts arguably involve particularly intensive research negotiations because of the low exposure to science through formal education and the media, and therefore greater challenges in understanding of research, and all its main tenets including individual consent. Livelihood struggles, poverty, and unmet health needs lead to researchers being confronted with numerous practical and often ethical dilemmas[3], with a lack of clarity in how to respond (Benatar 2002; Lavery, Bandewar et al. 2010; Molyneux, Mulupi et

[3] Meaning an apparent conflict of ethical values, see MacKay, E. and P. O'Neill (1992). "What creates the dilemma in ethical dilemmas? Examples from psychological practice." Ethics Behav **2**(4): 227-244.

al. 2012). FWs at the frontline of research implementation face these challenges upfront; how they respond to these issues is an area of scientific and ethical concern.

1.4 The study questions and objectives

My intention in this research was to describe the nature of research-related interactions between fieldworkers and study participants, and their influences, if any, on research participation. I formulated six objectives, which evolved over the course of the research to be, to:

1. Develop an overview of who the fieldworkers are in KEMRI-WT, including their roles, overall expectations and concerns with their position in the institution.
2. Describe two key areas framing the interactions between FWs and participants in the case studies: household decision-making norms around research participation; and participants' hopes and anxieties.
3. Describe the main challenges faced by FWs in their interactions with community members, and if and how these were resolved.
4. Describe emerging dilemmas for FWs in their interactions with participants, including those associated with silent refusals, levels of benefits and the development of social relations.
5. Explore the implications of fieldworker and research participant interactions for research implementation and ethical practice.
6. Develop recommendations for supportive supervision of fieldworkers in this and other similar settings.

I designed a mixed methods social science study to address the objectives. The study was primarily qualitative with the qualitative component exploring views and opinions

of the FWs; and of the researchers and the participants whom FWs worked most closely with. Much of the qualitative work was nested in two longitudinal community based studies, where I also had an opportunity to join the fieldworker teams in their fieldwork and their meetings with supervisors. The quantitative component of the research was a household survey aimed at providing an overview of the perceptions of community members towards FWs and the research centre.

This research is a social science descriptive study aimed at contributing to practical or applied ethics. The potential contribution of empirical social science research to bioethics is increasingly recognised but is also contested (Hedgecoe 2004; De Vries, Turner et al. 2006). Some of the contestation are about the different philosophical orientation of social science and bioethics; empirical social science studies address how things are, while philosophical bioethics is concerned with how things ought to be, the 'fact-value' argument (De Vries, Turner et al. 2006; De Vries and Gordijn 2009). Social science methods are also criticised for being subjective and only relevant to the context of the study; with reflexivity, so valued in social science studies, seen to mire philosophical reasoning (Hurst 2010). The arguments for empirical social science in bioethics include its strengths in complementing the reasoning and logic of philosophical ethics through assisting with unpacking and identifying ethical issues in different contexts (Ives and Dunn 2010); with assessing the application of ethical policies and guidelines in practice; and in evaluating the impact of normative arguments on practice (De Vries, Turner et al. 2006). My study falls under the spectrum of empirical social science, the main focus being to provide a description of fieldworkers roles at the interface of research implementation.

1.5 The interpretive framework

I used social constructivism as the interpretative framework of this research. Unlike positivism (defined in 2.2), social constructivism allows for multiple interpretations. It recognises that knowledge is co-produced, and that understanding of reality is dynamic; shifting over time, space and across different respondents (Cruickshank 2012). The meanings of research encounters and perceptions of research, for example, are co-produced between those interacting over the course of research, and the social space within which the interactions take place. How well the research activities fit in with, or disrupt, other activities, centrally influences that co-production (Morris and Schneider 2010). The results of my study are inevitably co-produced, by participants with others and with me, and informed by all of our perceptions, experiences and events, past and present.

1.6 Structure of the thesis

In this thesis, I present empirical findings in response to the objectives described above. The thesis is divided into 9 chapters. After this overview chapter, in Chapter 2 I cover the literature that forms the backdrop for this thesis, including ethical guidelines for biomedical research in developing countries, challenges in their application in practice, social relations and relational ethics in health research in developing countries, and the roles of fieldworkers in research conduct. The latter also covers strengths and challenges of working with FWs.

In Chapter 3, I discuss the context of this research, first describing the socio-economic indicators of the country, Kenya, and of the administrative region where the research centre is located, the Kilifi County. I then describe key features of KEMRI-WT, the

research centre where this study was conducted. Chapter 4 focuses on the research design and methodology.

The empirical findings are presented in Chapters 5 to 8. The contextual background information about fieldworkers at KEMRI-WT is covered in detail in Chapter 5. The findings presented in Chapters 6-8 are primarily based on data collected in the two community-based studies. In Chapter 6, I describe two important areas framing researcher-participant interactions: participants' hopes and anxieties; and household decision-making dynamics in research-related decisions. The challenges that fieldworkers encountered at recruitment, study consent, and in follow-up activities are presented in Chapter 7, including a discussion on 'silent refusals'; a strategy used by participants to negotiate favourable research participation.

The various strategies used to resolve challenges FWs faced, and the ensuing ethical challenges and dilemmas for FWs are discussed in Chapter 8. In Chapter 9, I bring together the main findings of the empirical chapters and discuss four interrelated issues with reference to relevant international literature; consent processes, study benefits, power and vulnerabilities in research conduct and FWs' roles as moral actors doing ethics in research conduct. I make suggestions for the type and nature of support for FWs and for the practice of research ethics in settings similar to ours.

Throughout the empirical chapters (5-8) I simply present the findings, without further discussion and reference to literature, unless where this is absolutely necessary. In the discussion chapter (9), issues that emerged across the empirical chapters are then discussed in more depth, and with reference to the international literature.

CHAPTER 2 Consent, community engagement and social relations; the central role of fieldworkers

2.1 Introduction

In this chapter, I cover the literature that forms the backdrop for this thesis. I begin with an overview of the ethics guidance for biomedical research, focusing on several principles with important implications for fieldworkers:

- respect for persons and informed consent, given that a key role of FWs is to conduct consent processes; and
- respect for communities and community engagement, given that FWs are constantly engaging with community members. With the lack of clarity in definitions and goals of community engagement, and the complex and contested nature of all of the key elements, employment of community members as research staff can also in itself be conceptualised as part of a wider set of community engagement activities.

Having provided an overview of guidance in these areas, I then describe challenges with the application of these principles in practice in developing countries. I comment briefly on the limits of consent and community engagement in terms of dealing with background hardships and inequities in many developing country settings. I then go on to discuss social relations and relational ethics in biomedical research (2.4), and fieldworkers as a central group of actors in biomedical research and in ethical practice in the field (2.5). Finally, I draw on the literature to present a justification for this research, and to present research objectives and the conceptual framework shaping this research (2.6).

The literature presented in this chapter was identified through recommendations from others, including at several international research ethics meetings. It was searched for in Pubmed using combinations of search terms including community research workers, research volunteer workers, peer recruiters, fieldworkers, laypersons, health research, and science. I also searched edited books, grey literature, and related references cited in the sources I identified by word of mouth and through literature searches.

2.2 Ethics guidance for biomedical research

A whole spectrum of health research types exist that are generally grouped into three distinct approaches, basic, applied and clinical research (Christakis 1992; Green and Mercer 2001). Biomedical research crosscuts these three main forms of research and is often positivist. Positivism emphasizes scientifically verified, logical or mathematically proven explanations in social and natural sciences (Baum 1995; Malterud 2001; Green and Thorogood 2007). The Council for International Organizations of Medical Sciences (CIOMS) defines research as:

> ...an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalisable knowledge (expressed, for example, in theories, principles, and statements of relationships) (CIOMS 2002 p 19).

Three[4] universally recognized *prima facie*[5] ethical principles guide the conduct of research involving human subjects, as outlined in various international ethical research

[4] While some guidelines describe three main ethics principles (e.g. CIOMs, 2002), other guidelines describe non-maleficence as a further ethical principles, (see Beauchamp, T. L. and J. F. Childress (2001). Principles of Biomedical Ethics. Oxford, Oxford University Press, Inc.)

[5] meaning that no single principle takes precedence over the others, but must be balanced against each other in any particular situation

guidelines, declarations and ethics documents (WMA 1979; Marshall 1986; Cassell 2000; Smith 2001; CIOMS 2002):

- respect for persons, including respect for an individual's autonomy to make choices about their research participation as a free agent (Flicker, Travers et al. 2007) and protection of those with diminished autonomy (CIOMS 2002);
- beneficence, which is about balancing harms and risks in favour of benefits (CIOMS 2002). Non-malfeasance is also considered a substantive principle related to beneficence in regards to a physician's obligation to a patient (or an investigator to a participant) to do no harm; and
- justice, which refers to fair selection of research participants. Underpinned by a distributive justice norm, this requires equitable distribution of both the burdens and benefits of research participation (WMA 1979; Flicker, Travers et al. 2007; Lavery, Grady et al. 2007);

In the following sections, I discuss respect for persons (and communities) as the ethical principles with immediate relevance to fieldworkers and their roles.

2.2.1 Respect for persons and informed consent

Informed consent is one of the most fundamental approaches to applying respect for persons (Boulton and Parker 2007; Chokshi, Thera et al. 2007). Informed consent incorporates five essential components: disclosure of all relevant information to potential participants; comprehension of information; ensuring participants have legal and mental capacities to make research decisions; freedom from coercion and undue incentives for prospective participants; and an explicit and formal consent often in written form (CIOMS 2002). Informed consent is premised on the notion that an

individual is a free autonomous agent, and that an individual's basic rights should be protected (Lindegger and Richter 2000; Lindegger, Quayle et al. 2007). These rights include the right of choice, of free decision making, of information and of self-determination (Lindegger and Richter 2000). One of the atrocities committed by Nazi physicians in World War II was to deny their victims these fundamental rights (Lindegger, Milford et al. 2006; Boulton and Parker 2007; Chokshi, Thera et al. 2007). Subsequently, ethical codes and regulations have primarily aimed at promoting individual human rights of self-determination through informed consent. For instance, the first of ten principles of the Nuremberg Code is on informed consent, stating that:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision..., (ORA Accessed 2011 Appendix IV (A)).

Informed consent discourses point to two, sometimes overlapping agendas, the legal and the ethical agendas (Chadwick 1997). The legal agenda is concerned with protecting the rights of self-determination for those involved in research, and addresses legal indemnity, protection, and insurance cover for both the researcher and the potential participant (Lindegger and Richter 2000). Informed consent under the legal framework attests that both parties (researcher and participant) entered into mutual agreement on the roles and responsibilities of one to the other. The preconditions for

valid consent under the legal framework include that consent is voluntary, the person consenting has the capacity to consent, and is of legal age and of sound mind, and that all relevant information has been provided (Lindegger and Richter 2000; Lindegger, Quayle et al. 2007). The legal framework provides judicial oversight for research conduct. In USA, for example, the legal oversight for research involving human subjects falls under the Food and Drugs Association (FDA regulation 21) and the Protection of Human Subjects (PHS) regulation 45, in the Code of Federal Regulations (CFR) part 46 and part 50 (WHO 2002). In Sub-Saharan Africa, South Africa has the most advanced regulatory framework for research under the Medical Research Council (Department of Health 2006). In Kenya, research is legally governed under the Science and Technology Act of 1979 (NCST 2005), but the health research and the national ethical guidelines are in their infancy, having been formulated less than five years ago. The judicial systems often use medical professional legal frameworks to redress research-related grievances. The inadequacy of legal frameworks for research conduct in these settings makes self-regulation and monitoring of research conduct crucial.

The second agenda for informed consent, the ethical agenda, underpins the ethical requirement to respect persons and their autonomy (Lindegger and Richter 2000). Two important conditions for respect for persons are; firstly, the individual must be treated as an autonomous agent, capable of making his/her own independent choices, and has the capacity to do so (Lindegger and Richter 2000; Boulton and Parker 2007; Miller and Boulton 2007); and secondly, that persons with diminished capacities are protected (Lindegger and Richter 2000). Informed consent under an ethical framework is a process, which focuses not on the result of a signed consent form, but on mutual understanding and cooperation between researchers and participants, culminating in a

choice made freely by prospective participants. The consent form is the tool for communication; the making of informed consent is a shared collaborative process of decision making (Lindegger, Milford et al. 2006). The emphasis on process recognizes several things:

- that making a decision about research participation is not a once-off event (Lindegger and Richter 2000; Benatar and Fleischer 2007; Boulton and Parker 2007; Chokshi, Thera et al. 2007);
- that potential participant's comprehension and understanding of the research is paramount (Bhutta 2004); and
- that researchers need to be aware of contextual and cultural situations that may hinder or conflict with the ethical requirement for individual informed consent, and find ways to address these (Lindegger and Richter 2000; Molyneux, Peshu et al. 2004; Lindegger, Milford et al. 2006; Manafa, Lindegger et al. 2007; Molyneux, Gikonyo et al. 2007).

Community engagement, discussed next, is one approach to strengthen ethical spirit of informed consent. Clearly, of interest for this thesis, and as discussed later in this chapter and referred back to regularly, is that conducting informed consent processes, and mediating between guideline requirements and ensuring real choices for potential participants, is a key role and challenge for FWs.

2.2.2 Respect for communities and community engagement

Respect for communities as an ethical principle stems from recognition of the social embeddedness of individuals in the communities they belong to, and the potential for unintended and unanticipated outcomes of research for individuals not directly

involved in the research (Benatar 2004). For example, some types of research, such as genetic research, inadvertently have direct implications for more than the individual participant (Foster, Eisenbraun et al. 1997). Communities can also have great influence on individual choices in some communities, especially in communitarian societies with strong emphasis on community values, connectedness, and identity (Benatar 2004; Weijer and Miller 2004; Mooney and Houston 2008). One of the practical ways to respect communities is through 'community engagement', described as an approach to involving communities in research. There are calls to add respect for communities as an ethical principle, operating at the same level as autonomy, beneficence and justice (Benatar 2004; Benatar and Fleischer 2007). Community involvement/engagement has historically been seen as particularly important in settings where there are major differences in language, cultural norms, values, skills, and access to resources and technology between researchers and research populations (Marshall and Rotimi 2001). These factors can make power differences more stark in relationships between investigators and participants (Marshall and Rotimi 2001; Quinn 2004).

It was noted in a recent international meeting on community engagement and consent in Kilifi, Kenya that researchers and research institutions have a range of goals or underlying values for CE. These can be broadly divided into those that are instrumental (for example, strengthening consent and science) and those that are intrinsic (for example, building appropriate levels of trust and respect), but that these aims are not always clearly articulated, and that there can be tensions between them (Participants 2011). In summary, benefits of community involvement/engagement in biomedical research are described to include:

- ensuring communities are informed of studies going on in the area and create better relations with the communities (Marsh, Kamuya et al. 2008; Nakibinge, Maher et al. 2009; Marsh, Kamuya et al. 2010);
- reviewing research designs and informed consent forms to ensure cultural and linguistic sensitivity (Morin, Maiorana et al. 2003; Diallo, Doumbo et al. 2005);
- improving understanding of risks, costs and benefits for participation in research, (Rotimi, Leppert et al. 2007; Tekola, Bull et al. 2009);
- closer scrutiny of research by the community and holding review committees (scientific and ethical) accountable (Cox, Rouff et al. 1998; Strauss, Sengupta et al. 2001);
- adding community voices to research institutions policies and activities (Edgren, Parker et al. 2005); and
- being responsive to community needs and priorities and countering community fatigue (Simon, Mosavel et al. 2007; Nakibinge, Maher et al. 2009; Davies, Mbete et al. 2012).

The main contestations with community engagement is around how to define communities, who represents communities, what exactly is 'engagement' and what depths of engagement are appropriate for biomedical research (Tindana, Singh et al. 2007; Marsh, Kamuya et al. 2011). I describe each of these in some depth in turn.

Defining communities

There is significant complexity in the term 'community', which generally describes a fluid, amorphous, culturally-constructed grouping of individuals (Simon, Mosavel et al. 2007; Tindana, Singh et al. 2007; Marsh, Kamuya et al. 2008; Tindana, Rozmovits et al. 2011). In the most straightforward definition, community refers to 'a sense of

belonging together' (Ragin, Ricci et al. 2008 p36). It may refer to a group of people living in the same locality, religion, race, profession or who share other common characteristics (Lavery, Grady et al. 2007). Membership of a community can be by choice (for example, membership in a voluntary organisation), or based on innate personal characteristics (for example age, geography, shared interests, values, experiences) (McMillan and Chavis 1986).

Many factors influence one's sense of membership to a community including emotional anchorage - leading to perceptions of solidarity- and cultural ties (CDC/ATSDR 1997). An individual can have a sense of belonging to more than one group in the community (Chavis and Florin 1990). Gusfield, cited in McMillan (1986), distinguishes between communities defined by their territorial and geographical proximities, and relational communities concerned with quality of relationships between individuals, and notes that there is much overlap between the two types (McMillan and Chavis 1986). A number of structural characteristics are associated with communities, including relative stability, social interactions and established institutions such as social support groups, neighbourhood networks, trade organizations, and community based organizations (McMillan and Chavis 1986; MacQueen, McLellan et al. 2001; Ragin, Ricci et al. 2008).

In health research, definitions of community have primarily drawn on the above definitions, and research needs, to include for example a common kinship, geographical locality, a certain disease or risk-factors, or people served by a particular health facility (MacQueen, McLellan et al. 2001). It has been noted, for example, that participation in research can create a community where those participating may develop a sense of

solidarity with each other (Mitchell, Nakamanya et al. 2002; Vallely, Shagi et al. 2007; Gikonyo, Bejon et al. 2008). For example within clinical trials, the very act of participating in research may establish mechanisms for information sharing, create bonds within trial participants, and exclude non-participants from such membership (Lavery, Grady et al. 2007). Such bonds and exclusions could go beyond the research period. Those excluded from research could also form a community based on their non-participation, for example, if they perceive they are unfairly treated by not accessing similar benefits to participants (Gikonyo, Bejon et al. 2008).

Generally, it is also recognised that a community can be defined internally, that is, an individual's own intrinsic sense of belonging, and solidarity with a group or community (Mitchell, Nakamanya et al. 2002; Mitchell, Nakamanya et al. 2002; Gikonyo, Bejon et al. 2008; Marsh, Kamuya et al. 2011). Communities can also be formed by external agencies for a defined goal (McMillan and Chavis 1986; Lavery, Grady et al. 2007; Ragin, Ricci et al. 2008; Kamuya, Marsh et al. 2011). Often, there is overlap between internally and externally defined communities, with some external agencies' efforts geared towards working within internally defined communities (McMillan and Chavis 1986; Marsh, Kamuya et al. 2011).

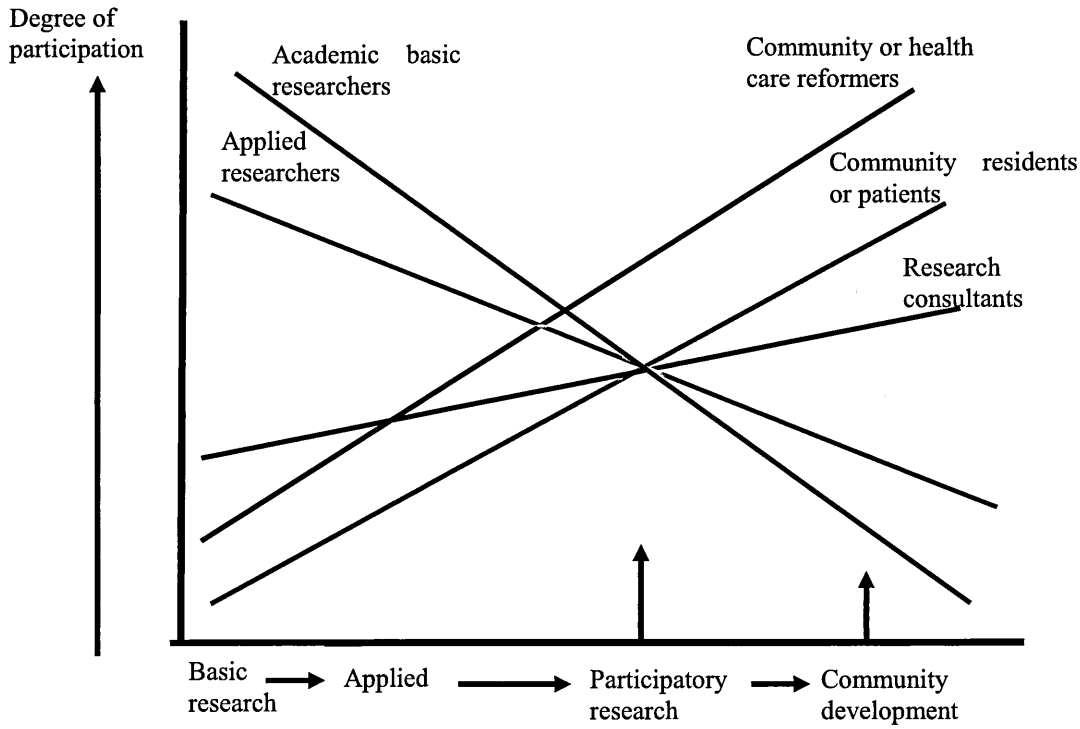
Defining engagement and appropriate depths of engagement

Community engagement or involvement in health research can be defined in many ways, but in its broadest sense it implies some form of interactivity between researchers and study communities (Weijer 1999; Weijer, Goldsand et al. 1999). It can be defined in terms of the depth with which a community is involved in a study. These depths range from simple information giving, through active consultation, to higher levels of

partnership characterized by joint decision-making, power-sharing and equitable involvement of stakeholders (Tindana, Singh et al. 2007; Marsh, Kamuya et al. 2008).

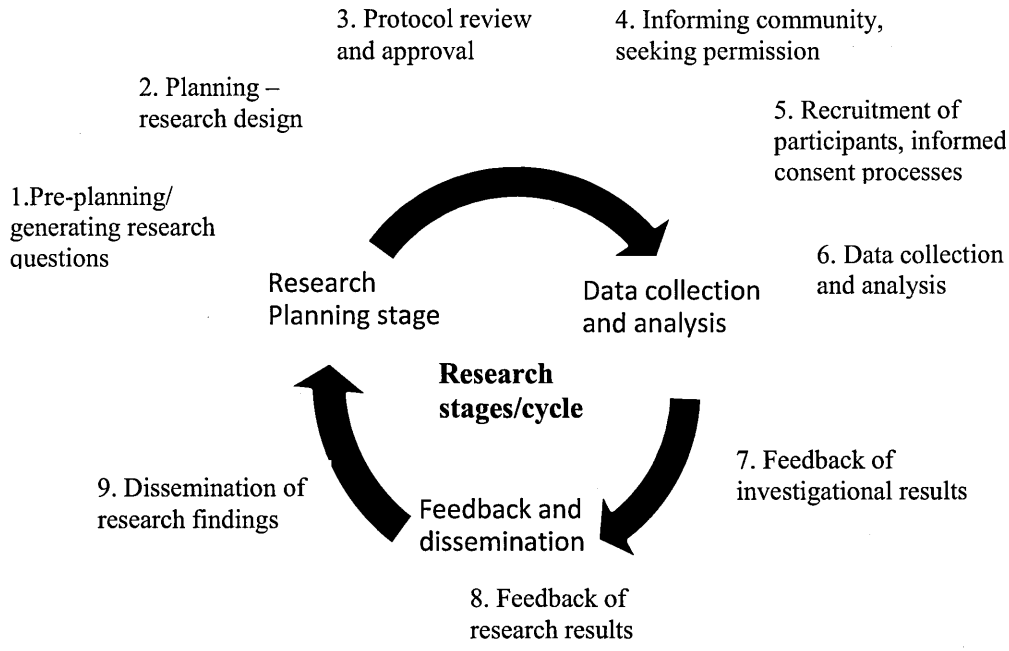
In research, the amount and depth of community engagement often depends on study type. Green and Mercer (2001) illustrated different levels of stakeholder (community) involvement for different types of studies (see figure 2.1), with highest levels of community involvement in participatory research and in community development and the lowest in more basic science research (Green and Mercer 2001).

Figure 2.1: Degrees of participation by different stakeholders and type of research



Amount, types and depths of community involvement could differ across the various stages of a study. Figure 2.2, shows the three main stages of a study – planning stage, data collecting stage and feedback of results stage - and the activities in each stage.

Figure 2.2: Summary of research stage and activities in each stage



Weijer et al (1999) describe a framework for planning community involvement at every stage of a study; protocol development, consent processes, data collection, access and storage of samples, dissemination and publication of research (Weijer, Goldsand et al. 1999). Through their research, they show that 'vulnerable' communities can potentially be protected through their involvement in research (Weijer, Goldsand et al. 1999). These views are supported by researchers involved in participatory types of research or where elements of participatory research have been used (Potvin, Cargo et al. 2003; Cargo, Delormier et al. 2008; Cargo and Mercer 2008; Shagi, Vallely et al. 2008). The appropriate level for involving communities in other types of research is, however, still contested.

Representation of communities in community engagement

Engagement with communities often involves interacting with either 'the general community' (however defined) or with some selected members or 'representatives' of those communities (Morin, Maiorana et al. 2003; Kamuya, Marsh et al. 2013). Formal mechanisms for engaging with communities typically include meetings with local leaders, administrative leaders, community-based organisations and the public (Weijer, Goldsand et al. 1999; Dickert and Sugarman 2005; Dickert and Sugarman 2006). Other mechanisms include inclusion of community members in institutional review boards, and the establishment of Community Advisory Boards (CABs) or variants of these (Diallo, Doumbo et al. 2005; Vallely, Shagi et al. 2007; Marsh, Kamuya et al. 2008; Shagi, Vallely et al. 2008; Nakibinge, Maher et al. 2009).

The information that is available is focused on Community Advisory Boards or Groups (CAB/CAGs), not least because such groups are increasingly recommended or required by research funders (Reddy, Buchanan et al. 2010). In many drug or vaccine trials, establishment of CAB/Gs has therefore come to be seen as 'standard practice' (Morin, Morfit et al. 2008). CAB/Gs can be from a broad cross-section of the community, that is, '*broad community*' CABS (Shubis, Juma et al. 2009), and/or from a particular population identified in a research proposal that is, '*populations specific*' CAB (Morin, Morfit et al. 2008).

Studies to date suggest a challenge in identifying who can be considered to 'authentically' represent communities (Morin, Morfit et al. 2008). As we have argued elsewhere, individuals might be selected or select themselves to *speak on behalf* of a particular community, or they may be selected on the basis of having similar

characteristics to the community of interest, and would then be speaking as 'typical' members of the community (Kamuya, Marsh et al. 2013). Representatives who speak on behalf of communities are often relatively charismatic, well known and outspoken, such as leaders of large women's groups or religious elders. These characteristics may make these representatives more able to voice their views and options, and ensure they are heard, but it may also mean they are rather unusual. Typical community members, depending on how typicality is defined, may be less well known and vocal, but may have greater contact with and awareness of everyday issues and concerns in their communities, including of the most vulnerable and marginalized members (Kamuya, Marsh et al. 2013).

As discussed in more detail later, although FWs are not employed formally as representatives of communities, they are often employed from communities where research is conducted, and are constantly interacting with community members in their daily lives and work. They are, therefore, informally engaging with communities all of the time. Also, given the lack of clarity in definitions and goals of community engagement, and the complex and contested nature of all of the key elements (described further in the next section), employment of community members as research staff can also in itself be conceptualised as part of a wider set of community engagement activities.

2.3 Challenges in applying ethics guidelines in practice in developing countries

While the principles informing the ethical conduct of research are considered universal, their application in different contexts potentially differs. A diverse range of guidelines

have been developed and revised to assist researchers and reviewers of biomedical research in applying principles. Emanuel et al (2004) distilled from existing literature and guidelines a series of principles and benchmarks for ethical conduct of clinical studies in developing countries. They present eight ethical principles and 31 benchmarks, many of which are related to consent and community engagement (see Appendix A). Although useful, empirical studies show that the way guidelines and benchmarks are implemented and work in practice is far from straightforward and sometimes have perverse outcomes. In this section, I highlight the challenges in practice with consent and community engagement. I then comment briefly on the limits of community engagement, including on handling the challenges related to appropriate standards of care and fair benefits, as these are an essential backdrop to FW experiences in implementing research.

2.3.1 Consent and community engagement

Significant challenges infuse all key components of consent for research in developing countries. Comprehension of research information and unfamiliar research terminologies, such as placebo and randomization, are areas that have received particular attention (Weijer 1999; Krosin, Klitzman et al. 2006; Lavery, Grady et al. 2007; Tangwa 2007; Upshur, Lavery et al. 2007). Voluntariness may be influenced by several factors including, individuals awareness of and ability to exercise their freedom to make choices, cultural norms, and background constraining situations such as unmet health care needs (Lindegger and Richter 2000; Nelson, Beauchamp et al. 2011).

Social desirability can also potentially threaten the validity of informed consent. Social desirability refers to situations where people behave and respond in ways they perceive

society expects them to, even if it is not what they want (Lindegger and Richter 2000). For example women may accept to be in research to avoid disagreements with their spouses, or with a researcher (Lindegger and Richter 2000; Molyneux, Wassenaar et al. 2005).

Therapeutic 'misconception' (TM), a perception that what is proposed in research is primarily aimed at an individual's health care and has a reasonable level of success, has been described to influence participants' consent to research all over the world (Appelbaum, Roth et al. 1982; Molyneux, Wassenaar et al. 2005). Closely related to TM, but aimed at challenging a tendency to overly attribute decision-making to TM, therapeutic fallacy in which participants expect researchers to prioritise their health care needs over research, can cloud participant's judgement of research (Kottow 2007). Even in the absence of therapeutic misconceptions, choices to join research can be based on accessing basic health care in a context of severely constrained health systems (Weijer 1999; Molyneux, Peshu et al. 2004; Benatar and Fleischer 2007). In a recent review, medical health care needs were identified as a source of pressure to participate in research (Mandava, Pace et al. 2012). Participants in developing countries in particular were found to be less likely to refuse or withdraw from the trial, and to be worried about consequences if they refused or withdrew.

As noted above, increasingly, *community involvement* in health research is seen as one way of addressing many challenges around ethical conduct of research in developing countries, including consent challenges. Ideally communities are involved not only as potential participants, but as health research stakeholders (Benatar 2004; Benatar 2004). However, community engagement activities remain focused on promoting

recruitment on early stages of studies (Diallo, Doumbo et al. 2005; Chokshi, Thera et al. 2007; Nyika, Chilengi et al. 2010). There are few studies that have evaluated the processes, outcomes and impacts of community engagement activities in research (Lavery, Tindana et al. 2010).

There are concerns that community engagement may not always bring about the positive results noted above in 2.2.2 (Marsh, Kamuya et al. 2010). For example, working with CABs can present some challenges including long, and sometimes acrimonious deliberations, and CAB members taking on roles that are not their mandate (NIMH 2008). Other practical challenges include low meeting attendance, conflict arising from different opinions, constituency affiliations and tensions around roles and remuneration (Vallely, Shagi et al. 2007; Shagi, Vallely et al. 2008; Shubis, Juma et al. 2009; Kamuya, Marsh et al. 2013).

The very process of involving community members in research consultation can raise fears and concerns unnecessarily, may confuse issues, could raise community expectations beyond what the research (and research institution) can provide, or increase refusal rates in studies as a result of misconceptions and misunderstandings about the research (Marsh, Kamuya et al. 2011). For a relatively dramatic example, tensions between researchers and community groups on HIV research in Nigeria and Cambodia resulted in these studies been stopped (Mills 2005). Reasons given were inappropriate mechanisms for communication and polarisation of issues by mass media (Page-Shafer, Saphonn et al. 2005).

Given the range of challenges described above for community engagement, and especially with regards to selection of and functioning of representatives to sit on formal structures, employed staff from communities in which research is conducted (or fieldworkers) can be drawn upon to contribute to some of the goals of community engagement bulleted out in 2.2.2. However, as paid employees of the organisation, fieldworkers' independence from researchers might be compromised. It is for this reason that employed staff are typically not formally considered as community representatives in community engagement strategies.

2.3.2 The limits of what consent and community engagement can achieve

While community engagement can strength research conduct in many ways, including in consent processes as has been discussed above, there is clearly a limit to how much it can by itself, achieve. Macro-level issues such as historical injustices, inequities, and unfair benefit distribution are an ever present background. Although community engagement may contribute to awareness of these issues, and to greater emphasis towards building approaches to redress these, these background issues and influences are likely to be beyond the remit of community engagement (Participants 2011). I discuss briefly two contested areas that research institutions and researchers grapple with in developing countries; and which are beyond what CE and consent processes can achieve: appropriate standards of care, and ensuring benefits to participants and populations are fair.

The appropriate standards of care during and at the end of research is an area that has received significant attention especially with the advent of HIV research (Weijer 1999;

Benatar 2000; Bhutta 2002; Wendler 2004). For externally funded research[6], areas of debate include: whether to provide best treatment available anywhere in the world (universal) or locally available treatment to participants in clinical trials; whether to use placebos when an effective treatment exists but is not locally available; and obligations of researchers to those who develop the condition under study during and after the research (Bhutta 2002; Benatar and Fleischer 2007; Ijsselmuiden, Kass et al. 2010). Despite amendments to guidelines in response to emerging thinking on standards of care, this area remains contested with regards to the scope of care against the resources required; and the potential risks of strengthening therapeutic misconceptions and undermining public health systems (Benatar and Fleischer 2007).

Debates around fair benefits

An area of growing discussion and debate in the literature is on distribution of the benefits of research among the range of stakeholders involved; researchers, research funders, participants, host countries and communities (Ballantyne 2008). What constitutes fair benefits, and the appropriate balance in benefits between micro level issues of justice and broader social determinants of health at the macro level is still contested (Countries 2002; Participants 2002; Ballantyne 2008; Macklin 2010; Molyneux, Mulupi et al. 2012). The nature of the benefits that can and should be provided over the course of various studies in different settings, and their mode of provision, remain ill-defined, as are the overlaps with obligations for ancillary care.

Clearly, the nature of research conduct in these settings requires critical reflection on how to handle injustices and inequities in unequal relationships, between the research

[6] For definition of externally funded research, see Ballantye (2008).

institutions and the communities in many of the developing world settings. For researchers in developing countries, background injustices of unmet health needs, poverty, and significant levels of diseases are issues they grapple with (Lavery, Bandewar et al. 2010; Molyneux, Mulupi et al. 2012). Fieldworkers at the forefront of research conduct, perhaps, often face these issues more starkly; they work with communities continuously and are members of the community themselves.

I now turn to the second area of interest in this research, micro and meso-level social relations and relational ethics in health research. Given that research participation involves human interactions, social relations, defined as connections that support relationships with others (Bajos and Marquet 2000) are inevitable. Later, I discuss FWs and their roles in research conduct.

2.4 Social relations and relational ethics in biomedical research

The importance of social relations for biomedical research has been highlighted in empirical studies (Fairhead, Leach et al. 2006; Fairhead, Leach et al. 2006; Gikonyo, Bejon et al. 2008; Leach, Fairhead et al. 2008). However, there is relatively little attention given to the types of interactions that foster respectful relationships and that facilitate ethical conduct of biomedical research. In this section, I first review literature that helps unpack social relations before discussing the centrality of social relations, and related relational ethics, in health care and in health research. This leads to a discussion of FWs in research as a group where research-related social relations with participants are part of, and emerge from, their work.

2.4.1 Conceptual framework for understanding social relations

Conceptual frameworks for social relations are helpful for unpacking interconnected and complex factors that influence how people behave towards each other in groups or in communities. Social network theories inform much work on social relations. Social network refers to how individuals or organizations are interconnected with others through interdependencies including friendships, kinships, resource mobilizations, and beliefs (Gottlieb 1985; Due, Holstein et al. 1999). As a grouping of individuals, social networks are opinion-forming spaces (Langford, Bowsher et al. 1997). There are two over-arching explanatory concepts in social networks; structure and functions (Due, Holstein et al. 1999). Network structure refers to relationships between individuals in the social network and includes both formal relations, that is, relationships by nature of one's position in the society; and informal relations, that is, linkages between individuals with whom one has close family relations and/or affection. Many factors influence the nature of relations, including the type of people in networks, the demographics of network members (such as age, gender and socio-economic status) and network features like frequency and duration of contacts, number of people in a network, and diversity of people in the network (Antonucci, Ajrouch et al. 1999; Due, Holstein et al. 1999).

Functions of social networks can be discerned from behaviours of individuals and the degree to which individuals identify with and are embedded in the network (Due, Holstein et al. 1999). Functions include activities that networks engage in and how strongly members identify with and support those activities (Langford, Bowsher et al. 1997; Due, Holstein et al. 1999). One of those functions is social support for members. Social support includes:

- the level of resources provided by others (Due, Holstein et al. 1999) and the affective (emotional) support received, provided or exchanged (Langford, Bowsher et al. 1997);
- social strain, or the extent to which social relationships cause emotional or instrumental strain, for example, from sharing resources; and
- social anchorage, which is the degree to which an individual identifies with and feels they belong to the network. Social support is expected to be reciprocal, with members in a social group participating in mutually rewarding activities (Cohen and Wills 1985; Ingersoll-Dayton and Antonucci 1988).

Emotional social support, described as the intangible emotional assistance given to others (Langford, Bowsher et al. 1997), is the most defining attribute of social support (Antonucci, Ajrouch et al. 1999) rendered through communication in which one is reassured of being cared for and valued. However other forms of social support include instrumental (material), informational and appraisal (Langford, Bowsher et al. 1997).

Studies show that social networks are important for pooling resources. Social groupings such as women groups and community-based organizations provide much needed social capital for health-related costs in constrained settings (Due, Holstein et al. 1999; Molyneux, Hutchison et al. 2007). They can also advocate and implement pro-poor health care changes such as cost waivers (Chuma, Okungu et al. 2010).

2.4.2 Relational ethics in health care and biomedical research

Consideration of social relations and relationships between researchers and participants, and how these may influence the ethical conduct of research suggests the

importance of relational ethics in biomedical research; that is, ethics informed by the context of the study, past histories and relationships between participants, the research team and the research institution (Geissler, Kelly et al. 2008). The importance of context has been highlighted by King cited in Quinn (2004);

> "...the ethics of human subjects research may be universal but is at the same time deeply particularized, so that what autonomy or informed consent or confidentiality or even benefit or harm means depends on the circumstances" (p921).

Relational ethics in health care

Relational ethics is based on the principle that people intrinsically care about each other (Gadow 1999; Larkin, de Casterle et al. 2008) and focuses on relationships as the centre of ethical interest (Evans, Bergum et al. 2004). It presumes that all human interaction is inherently value-laden and that humans relate to one another in particular ways (Evans, Bergum et al. 2004). Where people are intrinsically related through kinship, universal codes, principles and regulations that do not explicitly address relational ethics need to be applied sensitively, and context and individual engagement become as important as adherence to ethical models. Morally, professionals are obliged to go beyond "simply knowing the ethical codes of one's discipline" (Carper cited in Evans, Bergum et al. 2004 p461).

Relational ethics have been explored extensively in the medical profession, especially with regards to nursing care. Bergum and colleagues (2002), building on earlier work by Gadow (1999), present three contingent layers of relational ethics as:

- the descriptive context of the research;

- the abstract knowledge of ethical universalism (that is, universal codes and principles that guide much research as described above); and
- ethical engagement that is, the inherent or relational knowledge which builds on and encompasses both subjectivity and rationality, developed through dialogue between professionals and lay people (for example, doctors and patients).

Bergum and colleagues (2002) situate ethical engagement (relational ethics) as a complementary paradigm that fuses abstract (universalism) and descriptive (contextual) knowledge to provide a deeper level of understanding. They highlight four themes of importance for relational ethics in the nursing profession:

- the environment, which includes critical characteristics of health care systems and how these could affect nurses' relationships with each other, and with patients;
- embodiment, in which both scientific knowledge and human compassion/relationships are given the same weight;
- mutual respect, which includes embracing values and ideas of others as a means to develop deeper understanding; and
- engagement, as the development of an emotional connectedness between health care providers and patients, through which co-learning takes place (Bergum 2002; Bergum and Dossetor 2005).

Evans (2006) in supporting relational ethics concepts as discussed by Gadow (2002) and Bergum (1999), and applying it to genetic counselling, notes that one of the dimensions of relational ethics linked to ethical engagement is developing friendships, responding to individuals as unique human beings, and establishing honest reciprocal

relationships (Evans, Bergum et al. 2004). A second dimension is dialogue, which is going beyond information giving to co-learning, being open to possibilities of new understanding, and in which trust and respect develops. A third dimension is presence, the space for individual reflections of encounters, and seeing the patient as a whole person with a life before and after the encounter, with histories, and their own knowledge. In all of these papers, the focus appears to be the micro-level individual interactions between professionals and 'lay' people, where professionals are situated as responding not only to their professional requirements, but also to the contextual situation of their clients. This responsiveness is recognized as central to professional encounters, with relationships developed between the professional and client feeding into the encounter.

Incorporating relational ethics into research ethics

Community engagement activities as described above are said to be one way in which a relationship paradigm can be actualized in health research (Quinn, Gamble et al. 2001). Exploring perceptions of research towards institutions and of specific studies and how they shape understanding, and decisions about research (Molyneux, Wassenaar et al. 2005), adds another dimension of relationship-based ethics in research conduct (Quinn 2004; Gikonyo, Bejon et al. 2008). For example, involvement of community groups, coalitions and Community Advisory Boards (CABs) in research, in addition to interaction between study team members and research participants, can form bonds between these community groups and the staff interacting with them regularly, which adds insights into the nature of discussions. Similarly, members of a CAB/G can end up forming social support groups beyond the research activity.

Empirical studies are drawing attention to the centrality of relational ethics in research conduct. Geissler et al's (2001) study in The Gambia explored interactions and relations between the study team and participants, and between participants and the general community in the course of a large community-based malaria vaccine trial (Geissler, Kelly et al. 2008). The study showed that material exchange during the conduct of the study appeared to consolidate kinship-like relations between participants and the fieldworkers. The study was understood and constructed within the social spaces in which it took place. FWs' judgements of how to behave were not only guided by the study guidelines, but also by the nature of relationships with the participants. The nature of relationships between FWs and participants appeared to influence participants' perceptions of, and decisions regarding participation (Fairhead, Leach et al. 2006; Fairhead, Leach et al. 2006).

A previous study conducted at KEMRI-WT on community perceptions of a malaria vaccine trial found that social relations between the study team and participants, and between participants and non-participants, were important in shaping how the study was discussed, understood, and integrated into people's lives (Gikonyo, Bejon et al. 2008). Perhaps because of the levels of study benefits to participants, there appeared to be jealousies between participants and non-participants, and loyalties defined along lines of participation status. For example, participants felt that research feedback should not be shared with non-participants (Gikonyo, Bejon et al. 2008). These issues have also been documented elsewhere in Africa (Geissler, Kelly et al. 2008; Mosavel, Ahmed et al. 2011).

Relational ethics and ethical principles are thus presented as complementary rather than as separate or competing paradigms, with particular attention given to the nature of relationships and how they shape the research encounters. Relational ethics refocuses attention towards commitment of persons to one another, in addition to duties and obligations that principle-based ethics seem to focus on. Relational ethics recognizes the inter-dependence of individuals involved, and how relationships with others can influence one's decision. The nature of relationships, in these instances, is important (Bergum and Dossetor 2005). One aspect of this, respect for persons, was discussed in 2.2.1, under ethical frameworks for shared understanding of research at consent. Another relational aspect with significant attention in literature is trust, which I now turn to.

The importance of trust in research

In research conduct, the relational notions of respect, trust and power are enacted between and across various actors and stakeholders. One key aspect of social interactions and relations identified through the above studies as important in medical research is trust.

Trust is described as a relational notion between people (interpersonal trust), between people and organizations (institutional trust) and people and events (Gilson 2003; Goudge and Gilson 2005). Gilson and colleagues define one dimension of relational trust as contingent on goodwill of the trusted to care and act in the best interests of the trustor in situations of vulnerability (Gilson 2003). Trust can be intuitive (such as trusting in the goodwill of a stranger), based on previous experiences, or based on expectations that the one trusted will act in the best interests of the trustor in situations

of uncertainty (Hall, Dugan et al. 2001). Behaviours that are said to support trust include personal and technical competence, fidelity (behaving in the best interest of the trustor), truthfulness, fairness, reliability, openness, confidentiality and consistency (Goudge and Gilson 2005; Gilson 2006).

In biomedical research in developing countries, trust is a salient feature in relationships between and within study teams, research participants, the community and research institutions (Gilson 2005; Goudge and Gilson 2005; Molyneux, Peshu et al. 2005). Trust can influence the information people choose to believe, perceptions of specific studies and research institutions, and decisions around participation in research (Gilson 2003; Molyneux, Peshu et al. 2005). Commentators also caution that trust should not be exploited once established, that it is very fragile and once broken takes long to rebuild; and that some level of enduring scepticism is essential for healthy trusting relationships (Gikonyo, Bejon et al. 2008). Lavery (2007) discusses trust in biomedical research as an aid in decision-making based on a shared framework of understanding and comprehension of research between research participants and researchers. Trust ".....must be earned by investigators and felt by individuals and communities that consider participating in research" (Lavery, Grady et al. 2007 p275). Lavery et al (2007) argue that trusting relationships must precede valid decisions. There is therefore a need for better understanding of, and research around, interactions and activities that contribute to trusting relationships between study participants and researchers in situations of low knowledge and understanding of research (Lavery, Grady et al. 2007).

In exploring interactions and relationships between study teams and research participants, fieldworkers are an important group, as they work at the interface between

study participants and research institutions, and are key to the types and levels of trust that are built.

2.5 Fieldworkers: doing ethics in field

As noted above, context and relationships are very important to ethical practice, and ethical dilemmas and challenges might be particularly stark or complex in settings where there are differences between researchers and participant communities in language, culture and crucially access to resources. This is often the case in international collaborative research involving developed and developing (or low-income) countries. One approach to overcoming linguistic and cultural differences between external researchers and potential research populations is to involve local community members as employees (Fairhead, Leach et al. 2006; Gikonyo, Bejon et al. 2008; Molyneux and Geissler 2008). This can also contribute to community members earning an income.

2.5.1 Field workers: who they are and what do they do

The term fieldwork is used extensively across different disciplines. In anthropology, it is used to describe the scholarly work that includes complete immersion in a study population for an extended period of time, seeking meanings, and learning through experiences, formal and informal discussions, and observations (Wolcott 2005; Anspach and Mizrachi 2006). In other social sciences, it refers to the period of data collection, in which researchers use various methods such as interviews, observations and surveys (Ritchie and Lewis 2009).

Researchers from all disciplines carrying out scholarly work may include resident community members in the conduct of research. Residents are employed for practical and ethical reasons such as easy access to participants, in order to address language barriers, to provide employment to community members, or to advise on culturally appropriate ways to conduct research (Molyneux, Kamuya et al. 2010; Simon and Mosavel 2010). For many social scientists, recruiting and involving community members in this way is an approach to enter, understand, and learn about the cultures of the communities they study (Shimpuku and Norr 2012).

Table 2.1 summarises different categories of research workers who are from local communities, their roles and the strengths and weakness of involving them in research. Some common names used to refer to various categories of community members employed in research include community-owned resource persons (COPRs), community volunteers, village reporters, field assistants, enumerators, peer recruiters, fieldworkers, and community research assistants. The term fieldworker used in this thesis refers to staff recruited from the community where research is being conducted who are employed by the research institution or team. They are expected to be primarily accountable to the research institution that employs them. Excluded in Table 2.1 and in this definition are other types of community members involved in research, most notably

- community representatives such as CABS discussed in 2.2.2 who sometimes carry out some of the functions outlined for community research workers, but their primary responsibility is advisory to the research team on community issues;

- community health workers, with the primary responsibility of providing first aid health care services at community level and to link community members to health professionals (Suri, Gan et al. 2007; Standing and Chowdhury 2008); and
- researchers working within their community as senior researchers or principal investigators, because their role is much wider than interfacing with the community.

Across the categories of people who are defined as 'fieldworkers' in this study (Table 2.1), there are differences in the way they are recruited, the research-related roles they perform and whom they are accountable to. Compared to other research staff, FWs often have lower education levels and are offered monetary compensation (as per capita or wage) at a lower rate than those staff with high education qualifications. Their roles may include some or all of the following: identifying potential participants, communicating research information to participants, undertaking consent processes, and conducting simple follow-up activities. Some of the follow-up activities include undertaking simple non-invasive procedures such as body temperatures, blood slides, and administering questionnaires. They are also sometimes involved in giving research results and information at the end of a study to participants and community members (Mitchell, Nakamanya et al. 2002; Geissler, Kelly et al. 2008; Shagi, Vallely et al. 2008).

Table 2.1: Types of community research workers

Criteria	Village reporters, CORPS,	Peer recruiters and respondent driven sampling	Field workers, community based assistants
Selection	• Often nominated by community members or leaders;	• Initial/primary recruitee into study, recruitment based on research; • Identified due to membership to a social networks;	• Often recruited by researchers to carry out certain research activities;
qualifications	• Some minimum basic literacy levels	• Some minimum literacy requirements;	• Higher literacy levels compared to the other two types (e.g. secondary schooling);
Remuneration/ support	• Compensated per work done; other expenses reimbursed;	• Dual systems of compensation, as a research participant and for each participant recruitment;	• Remunerated as staffs of research institutions; some are paid per work, others monthly wages • Renewable contractual arrangements;
Roles	• Documenting events which have implications for research; • Sometimes involved in longitudinal demographic surveys to inform on births and deaths of the population;	• Recruitment of hidden or vulnerable populations, or where there is no existing framework for identifying potential participants; • In some situations, provide initial study information to potential participants;	• Initial information giving to potential participant and community members; • Advise researchers on local cultural and linguistic appropriateness of the research; • May be involved in engagement activities; • Can identify potential participants where there is no sampling framework; • Sometimes carry out simple non-invasive study procedure such as collecting urine, saliva, stool samples, taking blood slides; • Involved in filling of survey questionnaires;
Where based	• Based and live in the community they come from	• Work within the study population/social network;	• Often work and live within the population of the research;
Strengths	• Timely and easy access of community information; • May be considerably cheaper than full time employees;	• Belong to social networks from where research participants can be recruited; • Research provides gainful employment to the community;	• Have clear roles, and remuneration; • Easy access by participants, discuss study in comfortable interactive environment; • Guided by professional codes of conduct;

	• Can provide information on locally sensitive or taboo topics; • Easily accessible by community members; • Can be trained to carry out simple non-invasive procedures; requiring minimal supervision; • Form a cohort of community members exposed to research;	• Skills and capacity development from research can promote self-worth and status of recruiters; • Advise on culturally appropriate research conduct; • Promote research participation; • Opportunity for community members to discuss the research in interactive comfortable environments;	• Advise on culturally appropriate conduct of study; • Link researchers, participants and community members; • Provided gainful employment; • Form a cohort of community members exposed to research; • Capacity building and skills development, can promote their status and self-worth;
Weaknesses	• If not well supervised, can manipulate data to earn compensation; • Sometimes maybe poorly compensated; • Time commitment for other livelihood activities could derailed research activities;	• Could introduce bias on selection of participants (selecting only from his peers/social networks); • Potential to exploit participants to meet recruitment quotas; • Potential for horizontal exploitation by using research environment to further self-interest; • Could compromise privacy and confidentiality; • Potential for vertical exploitations through unfair employment practices and under payments;	• Potential to exploit participants to meet recruitment quotas and to retain participants (horizontal exploitation); • Potential to compromise privacy and confidentiality; • Interface role can be distressful especially in settings of vast unmet needs; • Could use research environment to advance self-interest; • Difficult to monitor their performance where based in their homes;
Main references	(Brieger and Kendall 1996; Jahn, Floyd et al. 2010);	(Abdul-Quader, Heckathorn et al. 2006; McKnight, Des Jarlais et al. 2006; Tiffany 2006; DeJong, Mahfoud et al. 2009);	(Simon and Mosavel 2010; Simon and Mosavel 2010; Mosavel, Ahmed et al. 2011; True, Alexander et al. 2011; Kamuya, Theobald et al. 2013);

Current debates on the ethics of employing community members in research studies point to potential ethical challenges. These include the possibility of exploiting trust bestowed on FWs by community members so as to attain recruitment quotas; and the possibility of compromising privacy and confidentiality entrusted in them (Gikonyo, Bejon et al. 2008; Molyneux, Goudge et al. 2009; Marsh, Kamuya et al. 2010). There are also challenges associated with whom they are most accountable to, the community they are members of, or the research projects which employ them. Other possible challenges include:

- encouraging participation for therapeutic rather than for research aims (Mosavel, Ahmed et al. 2011);
- encountering morally distressing situations because of the livelihood struggles in the communities they work within (Molyneux, Kamuya et al. 2010; Simon and Mosavel 2010; True, Alexander et al. 2011); and
- perceived unfairness in employment in ways that can lead to unethical behaviours, to safeguard their jobs, for example, falsification of research data (True, Alexander et al. 2011).

Some of the challenges FWs encounter are not easy to resolve, presenting dilemmas with no clear recourse, and with competing interests for community members and researchers (Molyneux, Goudge et al. 2009). Nevertheless, it is recognized that fieldworkers are important in bridging language and cultural barriers, and their continued presence in the community beyond the study duration can also enhance relationships between long-term research programs and local communities (Gikonyo, Bejon et al. 2008; Simon and Mosavel 2010).

One moral argument for employing community members in research is that providing employment can contribute to making the community better off than they were before the research (Simon and Mosavel 2010). In this regard, employing community members into research and building their capacities can be seen as part of wider benefits to communities. For community members involved in participatory research, where community empowerment is the goal, capacity building is a core element in the research activity (Cargo and Mercer 2008). In other types of research, academic training such as diploma or graduate-level training might be provided as part of capacity strengthening and to strengthen the social value of research for the communities involved (Cashman, Adeky et al. 2008).

A particular concern because of the potential threat to research ethics and data integrity is related to distributive justice for FWs; for example fairness in employment and remuneration, integration into the study teams and appropriateness of work environments. True et al, (2011), based on a study comparing FWs[7] with traditional research assistants, suggest that FWs were more likely to engage in wrongdoing or "misconduct" where there is poor integration into the study team, poor job security and low education levels.

Given that there is very little published data on working with FWs, I now turn to other community members involved in research to identify background areas of interest for FWs and this study.

[7] In the paper, FWs are referred to as community research workers (CRW)

2.5.2 Learning from other related groups

Despite different roles, systems and work environments, fieldworkers' issues and challenges described in the literature are comparable to some extent to those of CABS, Community Health workers (CHWs), and peer recruiters. CABs were discussed in 2.2.2. I therefore briefly discuss CHWs as one group of community members involved in health, and who share some of the characteristics of FWs of being embedded in the community they work in, and mediating between health professionals and community members. I then turn to peer recruitment, another system of participant recruitment described in the literature which draw similarities with that of FWs.

Community Health Workers

CHW involvement in health care provision became prominent after the Alma Ata declaration of 1979; aimed at addressing the gap between health needs and provision. A minimum requirement for CHWs is usually some basic literacy skill. They also undergo vocational training to provide a "menu of services under the supervision of qualified professionals" (Standing and Chowdhury 2008; Simon and Mosavel 2010). While CHWs can improve access to health care in remote areas, and have an understanding of and often an intrinsic motivation to serve their communities, challenges include (Standing and Chowdhury 2008):

- pressure related to the nature of their work, competence limitation, and emotional distress of working in hardship context encumbered with vast unmet health needs and limited resources;
- unclear demarcation of roles and ambiguity on whom they are accountable to;
- inadequate training, resources, supervision and compensation; and

- ill-defined relationships between CHWs and other health workers in supervisory roles.

In some hard-to-reach populations, or those without a sampling framework, CHWs have also been involved in research, particularly in new research populations without an existing framework, and as part of enhancing collaboration with the Ministry of Health. However, the same challenges have been raised. A further concern is that the incentives offered in research could potentially make CHWs prioritise research activities over the community roles (Angwenyi, Kamuya et al. 2013).

From the literature on CHWs and CABs, several points can be drawn that are important considerations for fieldworkers in heath research. Firstly, it is important to have clear understanding of their roles and to know whom they are primarily accountable to avoid confusion (see previous discussion in 2.5.1). Secondly, there is need to consider the workload and appropriate levels of compensations for FW. Thirdly, FWs require appropriate support to be responsive to field situations and appropriate skills to do their work (Mosavel, Ahmed et al. 2011; True, Alexander et al. 2011). Finally, FWs can be gatekeepers for the community, with both positive and negative consequences.

Peer recruiters and respondent driven sampling

Recruitment of research participants is often research-led. However, there are situations and circumstances where this is not always feasible, such as in hidden populations with no existing sampling framework, or for populations involved in illegal or stigmatized behaviours such as Men who have sex with Men (MSMs), intravenous drugs users (IDUs) and commercial sex workers (CSW). In these and other circumstances,

participants may be recruited by people they are closely linked with or who are known to them. Such is the case for respondent driven sampling and peer recruiters.

Respondent driven sampling (RDS) has in the last decade been widely used to recruit hidden populations (Standing and Chowdhury 2008). RDS was formulated in late 1990's by Hackethorn and colleagues to address challenges of recruiting participants in HIV studies, when HIV was a highly stigmatized condition (Heckathorn 1997). The RDS system is based on peer recruitment of participants from social networks, where the recruiter is a member of a social network. The first recruiter is usually the first participant, the 'seed', who then recruits other network members into the study.

A dual system of incentives for peer recruiters is used; they are compensated for research participation (as are the other participants) and for recruiting other participants (Abdul-Quader, Heckathorn et al. 2006). Incentives for recruiters could be in the form of a standard level of remuneration at the end of the study (for example, wages) or payment per person recruited (Heckathorn 1997; Abdul-Quader, Heckathorn et al. 2006). The latter, however, may encourage a form of horizontal exploitation in which the recruiters exploit trust in existing relationships to meet recruitment quotas (Landy and Sharp 2010). To curb these tendencies, recruitment quotas per recruiter are set. These also assist to avoid over-recruitment in a social network and breach of confidentiality (McKnight, Des Jarlais et al. 2006).

Peer-driven recruitment (PDR), a variant of RDS, was developed in 1996 initially in America to recruit participants into HIV studies (Tiffany 2006). Based on the goals of participatory research, PDR can involve few recruiters over a long duration or many

recruiters over a short duration. Where few recruiters are involved, they can be employed in the research institution staff, much like FWs. Their roles could include carrying out research activities in addition to recruitment of participants, such as follow-up of participants. Short-term engagement of a large number of peer recruiters may be based on the need to expose many community members to the research. Similar to RDS, PDR is based on social network theories and faces similar challenges of selection bias, potential threats to confidentiality and privacy (Tiffany 2006; Simon and Mosavel 2010).

Several points emerge that are relevant to FWs. Firstly, FWs can potentially recruit participants in populations they are members of, and which are hard-to-reach either geographically or socially by the condition that is being studied. Secondly, because of already existing relationships, FWs can potentially misuse trust bestowed on them by community members, to meet recruitment quotes.

2.5.3 Fieldworkers as a key group in community engagement and research ethics

As described in 2.5.1, employment of FWs in research activities can potentially strength conduct of the research through FWs' insider knowledge of the community. Fieldworkers are often viewed as mediators and cultural brokers of research and communities: community members may view FWs as the face of the study team and the research organization; while researchers may view FWs as part of the community adding 'community voice' into research activities (Gikonyo, Bejon et al. 2008; Geissler and Molyneux 2011:83-5). They are thus frequently consulted, formally or informally, on issues from, and perspectives of, the community (Geissler, Kelly et al. 2008). The

onus is often on fieldworkers to balance the requirements and expectations of both the research institution/team and the community. While formal mechanisms such as ethical codes and principles are expected to guide FWs in performing their roles, the interactions and relationships they form with research participants and community members (see 2.4) might also influence the ways in which they view and identify with the community (Gikonyo, Bejon et al. 2008). Applying a relational ethics lens to the work of FWs then seems important in unpacking the influences of relationships they are part of on the way their do their formal roles (Fairhead, Leach et al. 2006; Geissler, Kelly et al. 2008; Mosavel, Ahmed et al. 2011). There are now increased calls for research on this group of community researchers for these reasons (Molyneux, Kamuya et al. 2010; Mosavel, Ahmed et al. 2011; True, Alexander et al. 2011).

2.6 The focus of the current study and study objectives

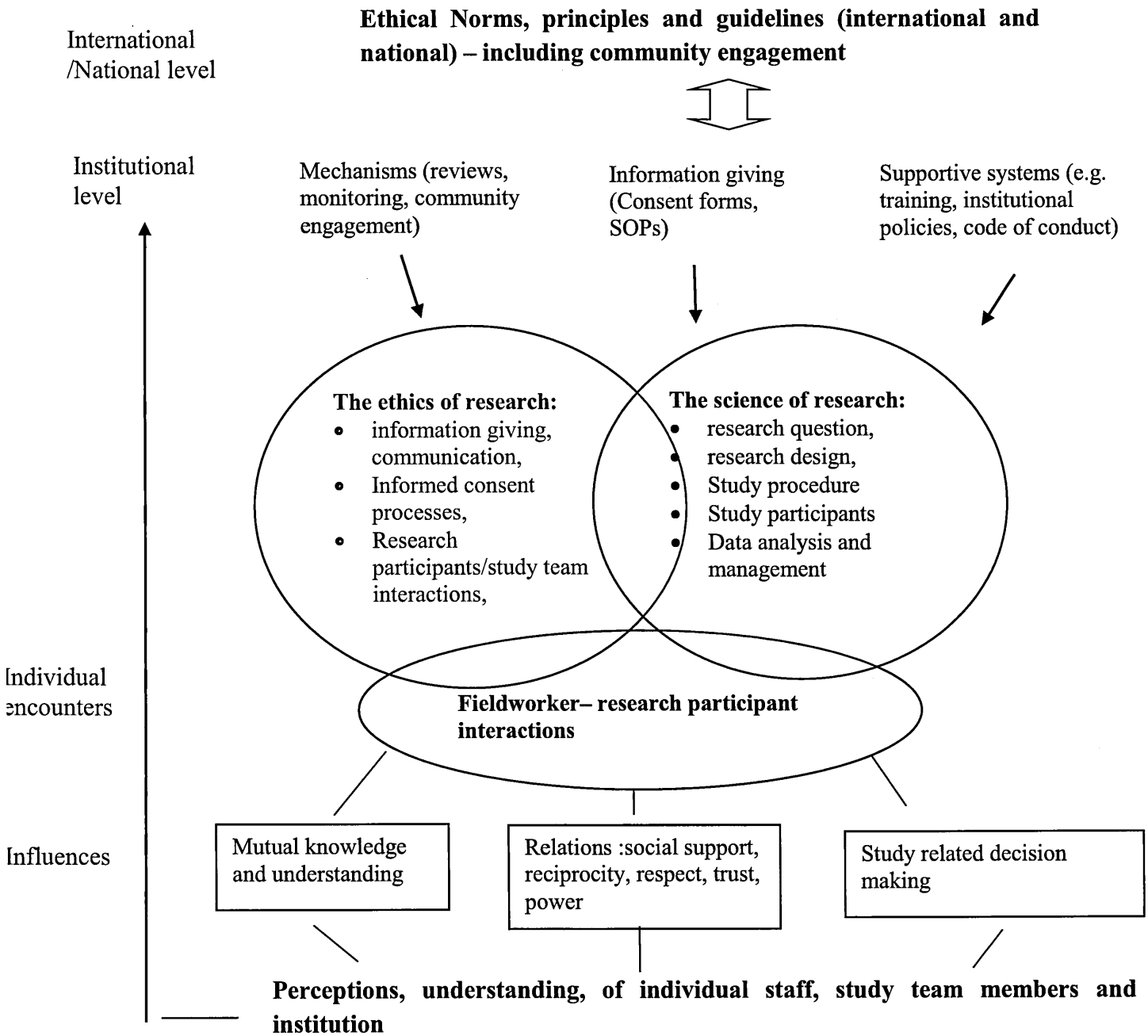
The focus of this study is the micro-level interactions between participants and fieldworkers, the influence that their interactions have on research participation, and the implications for ethical practice. Figure 2.3 shows the linkage between the macro-level guidelines for ethical conduct of research, the meso-level (institutional) systems and structures aimed at facilitating and supporting ethical conduct of research and the micro-level (FW-research participant) interactions. I discuss each of these levels in turn.

The three universal norms guide ethical conduct of research globally, as described in 2.2. Various national and international guidelines developed across different contexts aid their application. Empirical studies on research conduct across different contexts and on different emerging issues (such as HIV, genomic research) led to reviews of

many of the guidelines at the turn of century, and further reviews since then (see 2.3). Institutional level mechanisms such as community engagement and informed consent processes are designed to aid the application of universal ethical guidelines across different contexts. Empirical research on how these institutional/meso-level approaches are working can feed into discourses on universality of ethical norms, among other areas.

Ultimately, the universal and/or meso-level research ethics guidelines aim to guide micro-level research conduct and interactions between researchers (including FWs), and study participants (see 2.2.2). The immediate outcomes of these interactions are research-related decisions (to participate in research or not), and the nature of relationships of those interacting. As discussed in 2.4, some relational aspects such as respect, trust and power, can influence the nature of interactions between participants and FWs, including levels of information sharing, and ability to make research choices (Geissler, Kelly et al. 2008; Gikonyo, Bejon et al. 2008). Empirical research on micro-level interactions, in turn, can feed into institutional mechanisms of strengthening research conduct, and normative discourses on ethical research. The conceptual framework that I propose, discussed next, focuses on the micro-level individual interactions.

Figure 2.3: Role of FWs in strategies to strengthen ethical research



2.6.1 The initial conceptual framework

I developed an initial conceptual framework (Figure 2.4) to guide the design of this research, and the constituent parts of information necessary to address the six objectives presented in 1.4. At one end are the factors that may influence research-related interactions, which I grouped into three categories.

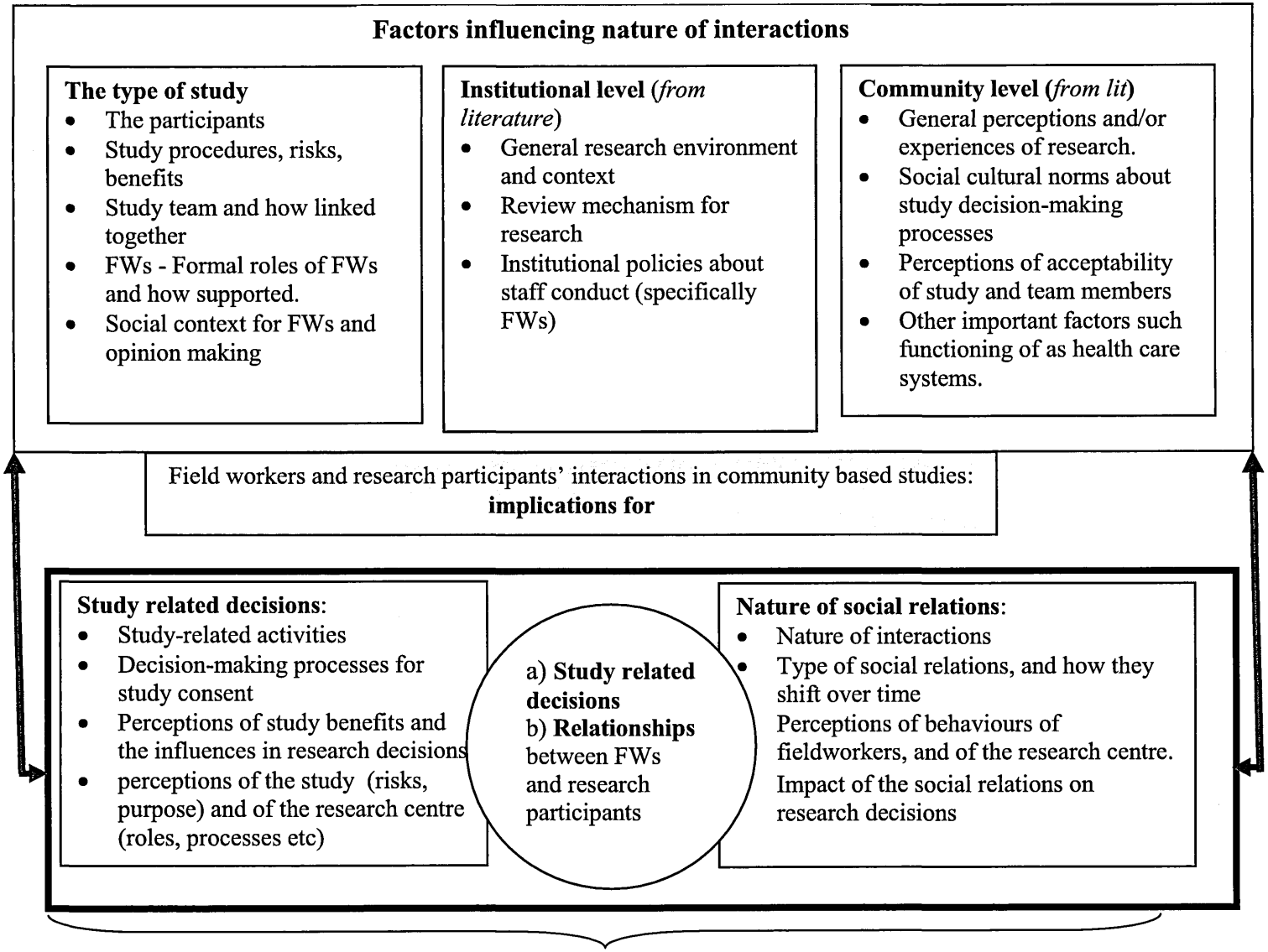
- First, those about the type of the study including, the study procedures, who the participants are, where the study is based, perceptions of risks, harms and inconveniences, and type, amount and scope of benefits (to individuals and to the community). These issues formed part of the criteria for selection of case studies for this research (described in 4.3).
- Second, the institutional level systems to support research conduct including the ethical review systems, guidelines around community engagement and consent processes, and employment and policies of training community members involved in research, including FWs.
- Third, the community influences including existing community relations with the research centre, past and current experiences of research, socio-cultural norms, and other factors such as the functioning of the health care systems.

These factors can in turn, contribute to two interrelated outcomes of interest to this study, research-related decisions, and type of relationships between participants and FWs.

I draw on social relations theories described in 2.4 to explore the nature of relationships between FWs and research participants, and the influence that these might have on research participation. In so doing, I recognise the complementariness of relational

ethics and ethics principles as described by Bergum and colleagues in the context of health care (Bergum and Dossetor 2005); and that the immediate interests of health care and research are different. Including a strong focus on research interactions post-consent is because this stage of the research has received relatively little attention. Consent processes, the first steps for involving participants in research, inevitably feature strongly in the study.

Figure 2.4: Initial study conceptual framework



2.7 Chapter conclusion

In this chapter, I reviewed the literature that informed the focus of this research, and provided justification for the research. The diverse challenges in applying research ethics guidelines across different contexts and communities underscore the importance of taking contextual factors and social relations into account in research conduct. There is wide acknowledgement of the challenges of conducting research in developing countries, among which are those related to consent processes and all its key elements.

Approaches aimed at addressing these challenges include designing locally appropriate consent and community engagement processes and employment of fieldworkers. How well these are working in practice, is an area of growing interest. It is also recognised that some of the challenges faced in developing countries cannot be tackled by consent and community engagement processes alone, requiring changes in benefits and macro-level inequities and injustices.

Employment of FWs has gained prominence in the literature in the last few years, particularly in research with hard-to reach populations. Fieldworkers' employment can be for instrumental and intrinsic goals: instrumental goals include ability to reach hidden populations, advising studies on local sensitivities, and communicating in appropriate language; and intrinsic goals include strengthening mutual understanding between the researchers/research institutions and the community, respecting community values, and providing employment to the communities involved in research. However, the very strengths of employing FWs can also present challenges and dilemmas. These include those related to confidentiality in research, and the potential for horizontal exploitation to meet recruitment quotas.

While community research workers have been involved in research for many years, few empirical studies have focused on FWs as specific area of interest. This study aimed to contribute to a growing body of literature that brings together two lenses for explaining research conduct, ethics principles and social relations. I developed a conceptual framework informed by the research objectives and the literature to guide the study design and tools.

The next two chapters describe the study context and design, starting with a description of the study site where the research was conducted (Chapter 3), followed by a detailed description of the design and methodologies used in this research (Chapter 4).

CHAPTER 3 Study site: Kenya Medical Research Institute, Kilifi

3.1 Introduction

The site of this research is the KEMRI-Wellcome Trust Research Programme (KEMRI-WT) which is one of the ten KEMRI centres mandated by the Kenyan government to carry out heath research. In this chapter, I discuss key population indices for the country and for Kilifi District, to provide contextual background of the site for this research. The chapter has seven sections.

Following a brief overview of the socio-economic and political context (3.2), and the structure of the health system (3.3), I describe the health research regulatory framework in the county (3.4). This is followed by an overview of the socio-economic indicators of Kilifi County (3.5), the types of research conducted at KEMRI-WT (3.6), and the institutional scientific and ethical review systems. I then describe two areas of interest in this thesis: the institution's community engagement strategy (3.6), and the 'fieldworkers' at the research centre (3.7). This leads to Chapter 4 in which I describe the research design and methodology used.

3.2 National socio-economic and political context

Kenya, with an area of about 582,646km^2 and a population of about 38.6 million in 2009 (KNBS 2010; KNBS. 2012) borders the Indian Ocean to the East, Tanzania to the South, Uganda to the West, and Sudan, Ethiopia and Somalia to the North (see Figure 3.1). Kenya is multi-ethnic, with more than 42 tribes, the majority of whom are Bantu-

speaking tribes who form nearly three quarters of the population, the rest being the Nilotes (a quarter of the population) and the Cushites (about 4%). Kenya is divided into 8 provinces, Coast province, of which Kilifi District lies, is the 6th in population size with 3,325,307 people (KNBS 2010). The coastal tribe of the Mijikenda, is one of the Bantu-speaking tribes with a population of about 1.96 million people (KNBS 2010).

Figure 3.1: Map of Kenya

http://www.vidiani.com/?p=8857

Since independence in December 1963, Kenya has largely been governed centrally, with planning, resource collection and allocation principally at central government through to sectoral Ministries. A few bouts of regional governance in the mid 1960's were quickly succeeded by a stronger centralized parliamentary governance system,

culminating in a powerful central government and reduced, almost defunct, regional counties.

The centralized government and administration structure is organized into seven tiers. In descending order of administrative functions, they include the central government headquartered in Nairobi, the provincial level and the district level, the latter being the reference point for planning and resource distribution. Under each district are the divisions, locations and sub-locations. With a new constitutional dispensation in 2010 that focuses on decentralization and devolution of ministerial functions, Kenya is currently at a transition phase with a hybrid system of partial devolution and gradual decentralization of public services. I started my research at a time when Kenya was on the verge of adopting a new constitution; and I finished my field research at a time that the new constitution had been adopted. As I write my thesis, the country is gearing up for elections in 2012/13, under a decentralized governance system, where 47 regional counties formed under the new constitution will be the seats of power. It is a period of high expectation of a new system of governance and fearful anticipation of an uncertain future following the post-election violence of 2008 presidential elections. These changes will have significant implications for health care governance, resource allocation and health care distribution in the country. It will also significantly affect regulatory frameworks for heath care research in the country.

3.3 Health system in Kenya and basic health indicators

Health care in Kenya is currently provided through the public sector and parastatal organizations, and the private sector, which includes private for-profit organizations, non-governmental organizations, and faith-based organizations. The public sector

accounts for 48% of health care provision, with nearly 7,400 health care facilities countrywide (Health Sector Working Group 2012). The Ministry of Health, under which health research falls, is being transformed alongside other ministerial changes under a devolved government structure. For example, at the time of starting my research, there was one umbrella Ministry of Health (MoH) under which health research was regulated. Under the coalition government, the Ministry of Health was split into two ministries, the Ministry of Public Health and Sanitation (MoPHS) - under which health research falls- and the Ministry of Medical services (MoMS). By the time of submitting my thesis, it is anticipated that the two ministries will have been merged back into one. Currently, even though formally health research falls under MoPHS, in reality researchers have to work with the two ministries because health research straddles both medical services and public health.

The health care delivery system in Kenya is organized along six health care delivery levels. Levels 1 and 2, community and peripheral health facilities, fall under MoPHS while the rest are under MoMS (NCAPD 2005). Health care facilities at level four (district levels) are managed by the District Health Management Teams (DHMT) and District Health Management Boards (DHMB). Health care priorities and budgets previously set at Ministry headquarters and cascaded to lower levels are now progressively been set at district levels with wider consultation at levels 1 and 2. However, there is still vast unmet health care need for the majority of population across all the six levels, particularly in rural areas.

Table 3.1 shows key health indices for the country. With infant, neonatal and under five mortality ratios of 31, 52 and 74 per 1000 live births respectively, and maternal

mortality of 448 per 100,000 live births, Kenya is ranked one of the countries with minimal improvement in health indicators in the past decade (WHO 2009). The cumulative number of health professional in the country is still low, with doctor and nurse to patient ratio of 16 doctors and 153 nurses per 100,000 population respectively, compared to WHO recommended minimum of 36 doctors and 356 nurses (NCAPD 2005). Given the nature KEMRI-WT work, it is not surprising that researchers encounter vast unmet health care needs of the population and have to find ways to work collaboratively with both health ministries, while also giving due recognition to the Ministry of Science and Technology which regulates all research in the country.

Table 3.1: Summary of Kenyan demographic indices

Indicator	Measurement
Demographics*	
Area	582,646km^2
Populations (2009*)	38,610,157
Annual population growth	2.9%
Population density	49 pr km^2
percent living in rural areas	32.3%
percent living in urban areas	67.7%
Health indices**	
Neonatal mortality	31 per 1000 live births
Infant mortality	52 per 1000 live births
Under five mortality	74 per 1000live births
Maternal mortality ratio	448 deaths per 100,000 live births
Life expectancy at birth	56 years
Economic/poverty indices***	
Percent living below poverty line	54%
Literacy rate among men	88.1%
Literacy rate among women	78.5%

* source: (KNBS 2010) ; ** Source: (KNBS 2010) ; ***Source: (KNBS 2005; KNBS 2006)

The contextual constraints of the health care systems in Kenya underpin the importance of research and KEMRI-WT strategic approach to supporting health care systems wherever it is conducting research. Headquartered within the Kilifi District Hospital (Level 4), and working across different health facilities in all the six levels of health care delivery, KEMRI-WT collaborates closely with the two health ministries.

Collaborative efforts have included having a dedicated liaison staff member, collaboratively identifying research agendas, working together to disseminate research results to policy makers, and helping to ensure translation of research results to practice. However, this process is long, with many competing interests and priorities.

3.4 Health research scientific and ethical review processes in Kenya

The shape and form the restructuring of the Health Ministries will take potentially has major implications for how health research will be conducted in Kenya, especially with regards to health research agenda setting, budgetary allocation, research governance and oversight. Health research funding in developing countries, and specifically in Sub-Saharan Africa, with the exception of South Africa, has been dismally lower than the 2005 Abuja targets agreed on, and the subsequent African Union target of 2% of the health budget (Kilama 2009). The Ministry of Health has a central role in redressing this balance, both in terms of political power and health research prioritization. Research agenda setting is however a contested area, with differing views on whether these are set within the country and influenced by other global health priorities. Weak government systems, inadequate government financing of health, inadequate health data that could inform research agendas, and poorly coordinated agenda setting structures are some of the challenges facing research agenda setting in many developing countries, including Kenya (Kilama 2009). Considerable power of multinational global health funders (government, public and commercial, and private funders of health research) means that research priorities do not necessarily reflect national or local priorities (Lairumbi, Molyneux et al. 2008).

Health research in Kenya was introduced alongside other health care services in around 1930's (Geissler and Molyneux 2011). Planning for health research priorities was mainly done at the Ministerial headquarters, with a focus on diseases that were prevalent at the time for the majority of the population, and especially those which were a menace to foreigners (Graboyes 2010). After the East African countries attained independence in the early 1960's, and with formation of the East African community, health research in Kenya, Uganda and Tanzania was overseen and driven by a regional ministry and implemented by the East African Medical Research Institute (Geissler and Molyneux 2011). With the collapse of the East Africa unity in 1978, Kenya formed its own governing body for health research, as was the case for the other two countries. A parliamentary bill, the Science and Technology Act of 1979, is the legal regulatory framework under which the National Council for Science and Technology was established. This is the umbrella body that coordinates all research in Kenya, including health, agriculture, and forestry. While the Act provides the parliamentary framework under which health research is carried out, the specific Ministries give the mandate for various institutions to carry out health research.

KEMRI, a parastatal under the Ministry of Public Health and Sanitation (MoPHS), is the government arm mandated to carry out health research in Kenya. There are currently 10 semi-autonomous KEMRI centres. Each centre is mandated to carry out research on key thematic areas. Each centre is semi-autonomous in that it falls under the policy guidance of the KEMRI Board and works under the broad thematic area of KEMRI research. Each centre can prioritize its own research agendas in consultation with relevant stakeholders, sources for funds and contributes to international scientific publications with minimal direct supervision from the KEMRI headquarters. The

institutional review process[8] for KEMRI includes two important and inter-related committees, a Scientific Steering Committee (SSC) consisting of all the 10 Centre Directors, and an independent Ethical Review Committee (ERC) (http://www.kemri.org/). Members of the ERC are drawn from different fields and include lawyers, religious leaders, community representatives, as well as scientists. The final decision of a research protocol is dependent on the ERC decision. Within each KEMRI centre, other subsidiary research review processes are instituted. As with other settings, the review process is important for ensuring that national interests are protected, that the research is relevant to the population, and that participants' rights are protected in research. Challenges with the review processes in Kenya, as elsewhere, include long duration taken in review processes, capacity for ethics committees to keep up to date with emerging ethical issues, and emerging innovative research and technologies with unanticipated ethical challenges (Molyneux and Geissler 2008; Nyika, Kilama et al. 2009).

Other institutions that carry out health research include hospitals, medical training institutions, universities, non-governmental institutions and private institutions (Lairumbi, Parker et al. 2011). As of 2008, only four institutions in Kenya, KEMRI, Kenyatta National Hospital, Moi referral Hospital and Aga Khan Hospital had an institutional ethical clearance/review mechanism (Lairumbi, Molyneux et al. 2008). Other institutions and individuals wanting to carry out health research had to collaborate with these institutions.

[8] By the time of writing this thesis, the ERC was undergoing transformation. The Ministry of Science and Technology was transforming the independent National Ethics Review Committee to an oversight body with mandate to oversee and accredit institutional ethics review committees

Several issues emerge from this description of health care systems in Kenya. First, as has been documented for other developing countries (Benatar and Fleischer 2007; Fowler, Adhikari et al. 2008), there are vast gaps of unmet health needs for the majority of the population, more so in the rural population (Chuma, Gilson et al. 2007; Chuma, Maina et al. 2012). Secondly, collaboration with the Ministry of Health is fragmented, with implications for coordinating research agenda setting and uptake of research results (Lairumbi, Molyneux et al. 2008). Thirdly, the regulatory framework for research in most developing countries is still at its infancy compared to developed countries, with concerted efforts in the past decade aimed at strengthening ethical review systems in developing countries (Chilengi 2009; Nyika, Kilama et al. 2009). Finally, these contextual factors contribute to potential for the exploitation of those already rendered vulnerable by unmet health needs and poverty (Mfutso-Bengo, Ndebele et al. 2008; Kilama 2009). Research review and oversight is particularly critical in these situations to safeguard against potential for exploitation of the communities (Emanuel, Wendler et al. 2004).

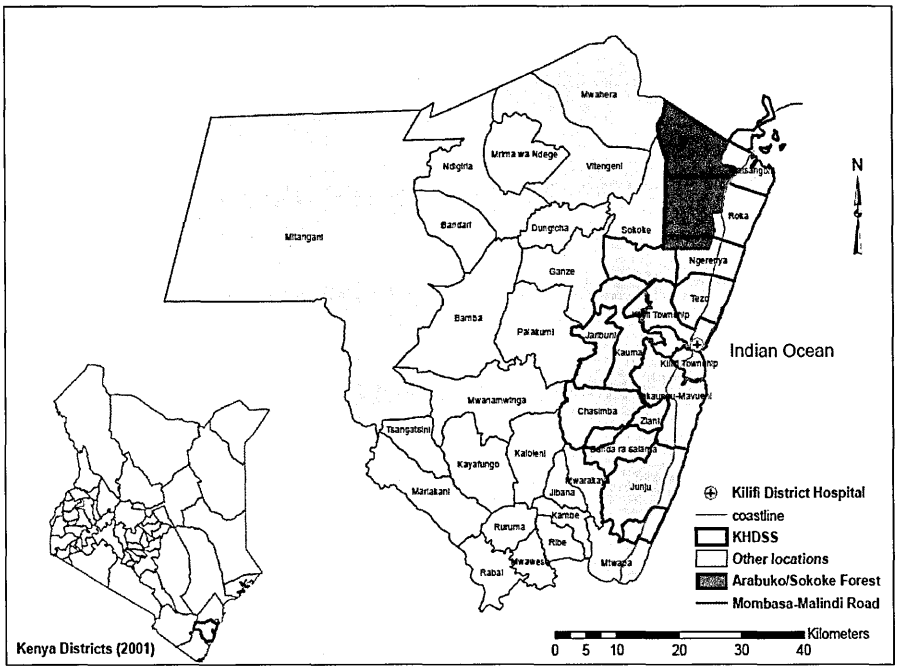
3.5 Kilifi District: Socio-economic and treatment-seeking context

The Kenya Medical Research Institute, Centre for Geographic Medicine Research Coast (KEMRI, CGMRC), also called KEMRI Kilifi[9], has its' headquarters in Kilifi District Hospital in Kilifi County (see figure 3.2). Kilifi Town is the county and district headquarters, nearly 60kms to the North East of Mombasa, the second largest city in

[9] KEMRI CGRMC is the name of the research centre as mandated by the Kenyan Government. The , centre director is appointed by KEMRI Board. KEMRI-WT is the research programme operating under the KEMRI CGMRC and headed by a scientific director. The most commonly used name is KEMRI Kilifi or KEMRI-WT. In this thesis I use the two names interchangeably.

the country. Kilifi County[10] is one of the largest countries of Coast Region, with a population of 1,109,735 and an area of 12,609km^2 (KNBS 2010). Figure 3.3 shows the Kilifi county and the area covered by the research centre's demographic and health surveillance system.

Figure 3.2: Map of Kilifi District and the KHDSS area



Source: Kilifi Health Demographic Surveillance System (KHDSS); 2012

Kilifi District[11] has an annual population growth rate of 3.17% against a national growth rate of 2.4%, a crude birth rate of 49.2 per 1,000, a crude death rate of 7 per 1000, under 5 mortality at 111 per 1,000, and life expectancy of 54-63 years, (KNBS 2010). Of the nearly 90,000 households in the District, with an average family size of 5.6 members, 67.4% are male-headed (KNBS 2006). Over 15% of marriages are polygamous (one of the highest in the country) and higher than the national figure of

[10] In this section, Kilifi County, instead of Kilifi District, is used because the latest census results are organized around counties. Three districts were combined to form the Kilifi county; Kilifi, Malindi and Kaloleni Districts.

[11] The information on vital health statistics have not been updated to county level, hence reference is made to Kilifi District where the figures are available.

11% (KNBS 2006). Literacy rates stand at 63%, with nearly a half-fold increase in literacy since the introduction of free primary education in 2003. Even though there is nearly equal number of boys and girls enrolled in primary education, few girls complete education, and fewer still progress to, and complete, secondary education (EPDC 2007).

The climate in Kilifi is hot and humid, with temperatures ranging between 22^0C and 35^0C. It receives unreliable[12] rainfall of about 400-1300mm per year with decreasing amounts of rainfall with increase in distance away from the coastal strip. The bimodal rainfall pattern includes short rains in October to December and long rains in March to July. Majority of the population relies on subsistence farming of semi-arid crops such as maize, sorghum, cassava and small livestock, mainly goats. Coconut, cashew nuts and fruit trees are grown along the coastal strip. In addition, tourism, fishing and small-scale trading are the main economic activities.

While 80% of household income is from agricultural activities, the district is generally food deficit with only 20% of food requirements produced in the district in 2005, which could only last for about 3 months (Food Security Assessment Team 2008). Most parts of the district are food deficit, relying on government food-aid programs. Kilifi Town, with a population of nearly 40,000 people, is the District/County headquarters, with KEMRI-WT being the largest employer in the district. Kilifi district is ranked one of the poorest districts in the country, with nearly 70% of its population below poverty line of Ksh.1562 per month ($22[13], or less than $1 per day) in 2005/06 (KNBS 2006).

[12] Estimated rainfall reliability of 60%, meaning that two-thirds of the time Kilifi County receives good rainfall.
[13] Exchange rate of $1 = 70 as of 2005/06 exchange rate

The Mijikenda tribe form the main population group in the Coast region, with seven of the nine sub-tribes resident in Kilifi County. Three of the sub-tribes, Chonyi, Kauma and Giriama are the main population groups in Kilifi District[14], with Giriama being the largest group. Other tribes and races are particularly common in the urban centres. The main religions include Christians (47%), Muslims (13%) and traditionalists (24%) (Kamuya, Marsh et al. 2013), with greater influence of Islam along the Coast. As is common in other Kenyan districts, Kilifi District is managed from two arms of the government, the Central government and the local (county) government, with the former being the formal administrative leadership recognised by the government, and by the community (Molyneux, Wassenaar et al. 2005).

Indicators of gender differences have been reported in Kilifi district to be amongst the highest in the country (Mensch and Lloyd 1998; Forde 2010). Gender relations within households are influenced by a whole range of factors including age, education, and household structure (Molyneux, Murira et al. 2002). Household in one compound can be grouped as follows (Parkin 1991; Molyneux, Murira et al. 2002):

- 'united households' composed of several nuclear families (also called extended households) who all cook and eat together and share responsibilities among members;
- 'partially divided' households where nuclear families live in the same compound, each cook separately but eat food together centrally; and
- 'divided households' where several nuclear families live in one compound but live separately largely due to some disagreements.

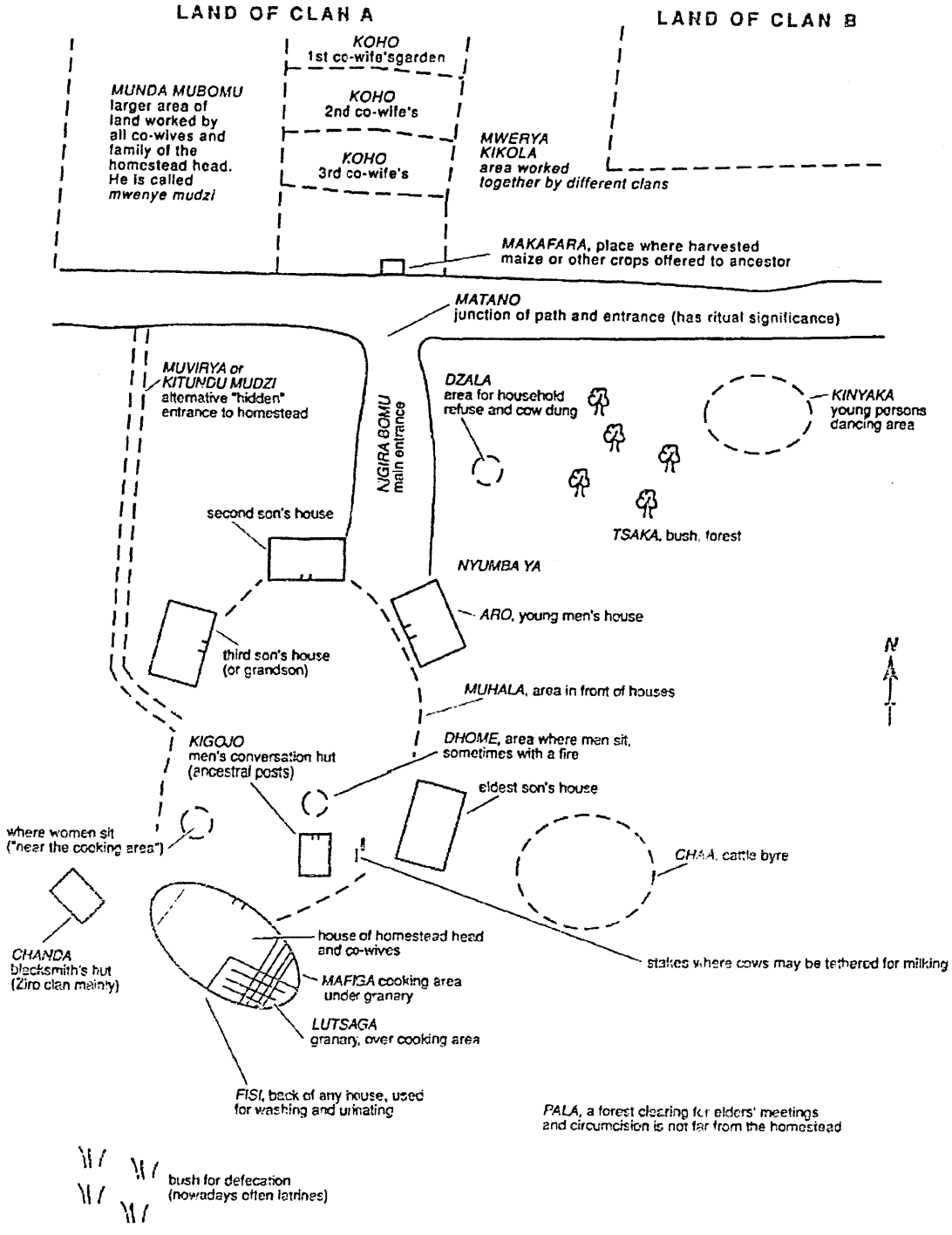
[14] Kilifi District is one of three districts that form Kilifi county, the other three being Malindi and Kaloleni Districts.

A typical extended-united household in Kilifi would be similar to Parkin's (1991) description, shown in Figure 3.3, although over the years there have been changes, with less visible demarcation of homesteads (Parkin 1991). For example, with strains on land, there is less intergenerational co-habitation in a household, and some of the functions such as 'dancing areas for young people', and allocation of huts to all sons in a household, are less common.

Molyneux *et al* (2002) studied treatment-seeking behaviours for mild malaria in children. They found that regardless of the living arrangement, generally men and elders (fathers, husbands, and sometimes elder sons) had normative authority over most decisions in the household including where, when and who sought treatment (Molyneux, Murira et al. 2002). They also found that age, gender, education level, migratory patterns, and nature of intra-household relations were important factors influencing distribution of decision-making powers and authority at the household in practice. For example, elder married women generally had more control over household activities than newly married ones or less educated women; those living within extended households had less decision-making power compared to those living in urban centres with their husbands. The study also found that women used various strategies to gain power and control over resources, including to circumvent "unpopular" decisions made by their husbands. For example, by gaining buy-in for their choices from other household members, covertly earning income or lying about the amount of income earned to safeguard against having to pool their cash into household income (Molyneux, Murira et al. 2002).

This arrangement of gender roles is also noted in other patriarchal African communities (Kandiyoti 1988), with recent studies showing changes towards more decision-making powers and control over resources to women, supported by gender-responsive structural changes, increasing literacy levels and income among women (Molyneux, Murira et al. 2002; Theobald, Tolhurst et al. 2006; Tolhurst, Amekudzi et al. 2008). Understanding the changing decision-making dynamics at households is important in research because research participation includes considerable decision-making processes, at consent and post-consent, as described in 2.2.1.

Figure 3.3: A Giriama homestead layout (Parkin 1991 p113)



3.6 KEMRI-WT, the research centre

KEMRI-Wellcome Trust Collaborative Research Programme is a long-term biomedical research centre established in 1989 as a parastatal (http://www.kemri-wellcome.org/). It has multidisciplinary research ranging from laboratory-based research studies, to clinical, psychology, epidemiology, immunology, entomology, public health, and social and behavioural research. Many research activities are conducted within the surrounding communities. A Kilifi Health Demographic Surveillance System (KHDSS) of nearly 260,000 residents was established since 2001, with the nearly 30,000 households surveyed three times a year. Data collected includes residence, migration, births and deaths (Scott, Bauni et al. 2012).

The main activities and offices of KEMRI-WT (see Photo 3.1) are within Kilifi District Hospital (KDH) where research and treatment activities are conducted in tandem (Scott, Bauni et al. 2012). A collaborative working arrangement with KDH management committee and those of peripheral health facilities has made possible long-term strategic support, and research integrated into the health care system. KEMRI-WT boosts clinical services and infrastructural development to contribute to a supportive environment for research, and to addressing the vast unmet health needs for the majority of the population. The support is available to anybody using the health facilities regardless of their involvement in research. The efforts are to ensure adequate standards of diagnosis and treatment particularly for the paediatric population who are most vulnerable to diseases and from whom research participants are commonly drawn. Efforts are constantly made to ensure that clinical services required for specific studies are provided in a way that is not undermining of the health care system, and that does not make stark differences between those in the research and those who are not. The

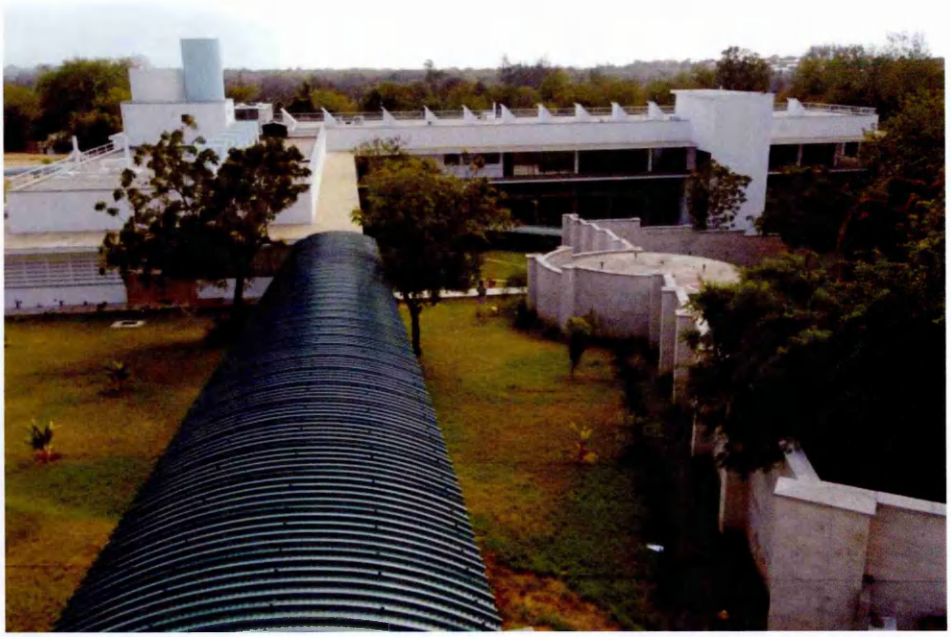
latter would undermine voluntariness in research. These efforts are not widely described in local communities and the vast majority of the population living locally might not be aware of them.

As with all KEMRI centres and as described above, all studies conducted by the programme are approved by the national SSC and ERC (Boga, Davies et al. 2011). For the KEMRI-WT, a prerequisite for national review is protocol approval by the local institutional review committees, which includes:

- a Scientific Coordinated Committee (SCC) consisting of all researchers and the District Health Management Team (DHMT). The SCC reviews all research protocols for the science and the ethics, once a month; and
- a Consent and Communications Committee (CCC), a subsidiary of the SCC, that reviews the informed consent forms for language clarity, inclusion of all relevant information and accuracy in translations to Kiswahili or the local language, often Giriama (Boga, Davies et al. 2011).

Other review mechanisms include those of collaborating institutions, especially for multi-site studies, or those required by donors.

Photo 3.1: KEMRI-WT offices at Kilifi



http://www.kemri-wellcome.org/

3.6.1 Community engagement activities at KEMRI-WT

In 2001, a study looking at KEMRI-WT interactions with the local community[15] looked at levels of understanding of research, community members' perceptions of the appropriateness of individual informed consent procedures and the role/involvement of husbands and community leaders in research (Molyneux, Peshu et al. 2004). At the time of the study, the majority of people were consenting their children to participate in on-going research studies, but it was not clear whether this consent was fully informed (Molyneux, Peshu et al. 2004). The study findings had major implications for the research programme, leading to policy and structural changes in the way the research centre interacts with the community, the institutional review processes, support to informed consent processes, and the employment and support for fieldworkers. I discuss three areas of greatest relevance to my study: understanding of research across the community, perceptions around informed consent, and trust as a relational notion.

Understanding of research

The study found that many people appreciated the work of KEMRI-WT and viewed it positively (Molyneux, Peshu et al. 2004). However, these positive views were often based on a perception that the research centre's activities are provision of health care. It seemed that consent for research was sometimes then given on an understanding that it was for individual health check, as opposed to research, referred to as a 'therapeutic misconception'. This was noted at the time to be a problematic term given that there are often genuine therapeutic benefits associated with research participation (Molyneux,

[15] At the time, the research centre was commonly referred to as 'The Unit'. Since its expansion across different geographic regions and study types, this has changed to KEMRI-Kilifi.

Peshu et al. 2004). A number of factors contributed to these perceptions, including similarity in processes of research and treatment; collection of similar samples as those used in medical care (such as blood); the centre's activities being established largely within health care facilities; and the lack of local terms for research and research-related terminologies. There were a range of rumours and concerns associated with unclear understanding of research and its procedures, with unusual behaviours by researchers such as collecting samples from well children in homes, and concerns about the relative wealth of the research centre, among others (Molyneux, Peshu et al. 2004; Molyneux, Peshu et al. 2005; Molyneux, Wassenaar et al. 2005).

Perceptions of appropriateness of individual informed consent processes

There was a spectrum of views with regard to appropriateness of informed consent for community based and for inpatient studies. For community-based studies, the majority of community members supported seeking permission from the formally recognized administrative leaders in the community, especially the chiefs[16], in addition to the other administrative arms of the government, that is, the District Commissioner and the Divisional Officers. This is because the chiefs were important gatekeepers for the community, entrusted to watch out for community interests. In regards to consent for research, however, permission from leaders was insufficient and consent from homesteads (households) and individuals was preferred, with majority of the community members favouring consent from male household members (Molyneux, Peshu et al. 2005). It was also suggested that the power of female members to make

[16] Chiefs are administrative leaders employed by the central government, with at least 12 years of schooling. They are residents of the area they represent. They administrate a location (a geographic area with an average of 10,000 people) while the assistant chiefs jurisdiction is a sub-location. Each assistant chief is supported by village elders who are nominated by the population and appointed by the chief. With the change in governance structure, the place, role and position of the chiefs and assistant chiefs is highly contested, with some suggestions that these structure will be scrapped, and the functions taken up by the county government.

consent decisions depended on education levels, control over income and other resources, and their relationships with husbands and elder household members. Seeking consent from participating children, however, was most often dismissed as inappropriate, especially for children of less than ten years, because they were perceived incapable of making independent decisions; male parental consent was often preferred (Molyneux, Wassenaar et al. 2005). For in-patient studies, the majority preferred to be informed about clinical investigations, however the views were quite varied with regards to seeking research consent. The appropriateness of seeking consent depended on severity of illness, level of understanding of those consenting, complexity of information, and the type of procedures involved (Molyneux, Wassenaar et al. 2005).

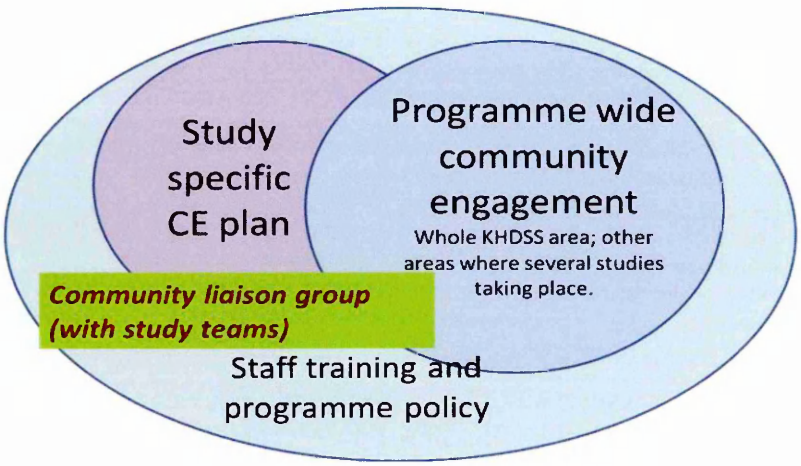
Trust

With regards to trust, the studies found overwhelmingly positive descriptions of KEMRI-WT and its work, and broad trust in the research centre, which appeared to contribute to high levels of consent (as opposed to refusal) for research at the time (Molyneux, Peshu et al. 2005). The basis for trust appeared to be an understanding of KEMRI-WT as hospital providing high quality health care, and as an aid organization helping the "poor" community (Molyneux, Peshu et al. 2005). There were very few descriptions that suggested an understanding of KEMRI-WT's work as health research, meaning perceptions of physician-patient relationships between KEMRI-WT researchers and community members (participants) and therapeutic misconceptions underpinned broad trust in KEMRI-WT. There were also elements of mistrust associated with unfamiliar research activities such as failure to provide 'individual' results during and at the end of a study (Molyneux, Peshu et al. 2005); and rumours

surrounding KEMRI-WT's work, associated with community members' attempt to make sense of difficult research concepts (Molyneux, Peshu et al. 2005).

These findings, and ensuing recommendations to improve communication between the research centre and the community, contributed to efforts and policies to strengthen community engagement at the programme (Marsh, Kamuya et al. 2008); with two main focus areas for most of the community engagement work (Figure 3.4); support to specific studies requiring community engagement, and programme-wide community engagement activities, described next.

Figure 3.4: Coordination of community engagement at KEMRI-WT



Programme wide communication strategy, including community engagement

A formative study conducted in 2004/2005 to contribute to the communication strategy for the research centre included consultations with various key stakeholders in and outside the programme, including people with diverse expertise such as ethicists, communication experts, policy implementation, and community members. The

strategy, which we have described in Marsh et al, 2008; has three broad goals: to build partnership and appropriate levels of trust in the institution, to meet ethical and good clinical practice and to ensure program sustainability (Marsh, Kamuya et al. 2008). Three levels of increased interactivity and engagement include within KEMRI-WT, with the community living in and around the KHDSS area and with the main health stakeholders including the Ministry of Public Health & Sanitation and Ministry of Medical Services (Marsh, Kamuya et al. 2008). The three areas form the broad focus for community engagement for the research centre. In reference to the community that is often involved in research activities, a range of mechanisms have been established to increase depth and levels of engagement (Marsh, Kamuya et al. 2008):

- regular interactions with administrative leaders (chiefs and assistant chiefs) and community opinion leaders (for example, village elders, religious leaders, CBO leaders);
- periodic (about once every 2 years) public meetings across the whole KHDSS organised around a key area of interest; and
- establishment of an additional network of 220 elected community representatives, KEMRI Community Representative (KCR). The KCR network is spread across the whole KHDSS and holds regular consultative meetings with the Community Liaison Group- CLG, see below. Meetings between KCRs and study PIs are organized as per need. An evaluation of this network showed that members were representative of the community in terms of gender, but were slightly older and better educated (Kamuya, Marsh et al. 2013). The longer their involvement with KEMRI-WT activities, the less typical of the wider community they became. In addition, it showed that resource negotiations took considerable amount of meeting time; and that KCRs frequently requested for additional more pro-active roles. A

current group of KCRs have been elected directly by community members across the whole KHDSS, with emphasis on members being typical of their community at the locational level (an administrative geographic unit). Current members have different education levels (including some who have never gone to school) and provide gender representation.

- FW training: Field workers at the research centre form the largest group of KEMRI-WT employees. As the interface between the research centre and the community, their place and importance has been recognized over the years in research and practice (Molyneux, Kamuya et al. 2010), as discussed in 3.6.2.

The range of community engagement activities are supported by relevant materials like leaflets and videos. Photos 3.2 – 3.7 show community engagement activities carried out at the research centre. In addition, and in response to requests from the community, a school science engagement project is being piloted in secondary schools, and is expected to expand to wider coverage with further funding (Davies, Mbete et al. 2012).

The communication strategy was planned as an action research activity with on-going monitoring and evaluation activities (Marsh, Kamuya et al. 2008). Monitoring and evaluation consists of three broad set of activities; a) pre-intervention baseline survey and research designed to feed into the development of the communication strategy, which was conducted in 2004/2005, b) post-intervention evaluation activities planned for 2011 – 2012 and c) on-going action research aimed at documenting and assessing the successes and challenges around specific community engagement activities. Some of the action research activities that are relevant to this study include the post-interventions survey carried out in 2011, in which I managed the data collection

activities, and oversaw cleaning, entering the data and analysis of part of the data. I added questions to the survey tool to gather information on respondents' perceptions of regularity of interactions with KEMR-WT staff and the nature of relationships between the community and FWs. This is discussed in detail in 4.4. The relevance of this information to the communication strategy is that it feeds into the evaluation activities with a focus on the role of FWs at the interface of research implementation.

Monitoring activities include careful documentation of all community engagement processes at the programme level and for specific studies. On-going research activities include published empirical work on a malaria vaccine trial (Gikonyo, Bejon et al. 2008), implementation of the communication strategy (Marsh, Kamuya et al. 2008), a preliminary evaluation of the KCR network (Kamuya, Marsh et al. 2013) and an on-going study looking at social and ethical implications of genetic testing in genome-wide studies (Marsh, Kamuya et al. 2011). Some of the findings from this research have pointed to the need for careful weighing up of the pros and cons of giving detailed study information at public community meetings. One of the concerns is that too much information can lead to "crowding out" where members pick elements of the information that seem most interesting and relevant, and make sense of them in ways that could be quite different from what was intended (Marsh, Kamuya et al. 2011). Work presented in this thesis will – and already has been –feeding into on-going community engagement processes.

Photo 3.2: A large meeting with community members in one of the KHDSS locations

Photo 3.3: Including edutainment[17] by a local group in CE activities

Photo 3.4: KCR meeting at the community

Photo 3.5: Health Action day in collaboration with district health stakeholders

Photo 3.6: Training of KCR members held at the research centre

Photo 3.7: Participatory training of KCR members

[17] A form of entertainment with educational messages targeted to a certain audience. Folksongs are popular entertainment media with key messages often integrated into the songs.
Consent was sought and given for all the photos used in this thesis.

Coordination of all community engagement activities at the programme

A group of staff, the Community Liaison Group (CLG) coordinates centre-wide engagement activities, and advises specific studies on community engagement at every stage of a study. Issues arising from the community are fed back to relevant departments and study PIs. In addition to the changes to the community engagement strategy discussed above, a number of institutional policies have been implemented in recent years, largely in response to issues learned from the communities. These include development and adoption of community engagement guidelines for the research centre, the establishment of a pro-active coordinated response to community issues, and the development of explicit employment policies for local staff. The latter includes recruitment of fieldworkers, where possible, from a specific locality where a study is based, given that employment is such a key priority and concern in this low-income environment.

Study specific community engagement activities: the cast team

For each approved study that has a community engagement component (which is reviewed alongside the ethics and scientific review), a CAST (Communication Advice for Studies Team) is formed to advise and support CE activities. The members are drawn from CLG, the study team and social science researchers; including at least a FW or a FW supervisor from the study team. The study PI chairs the CAST meetings; which are held as required by the study team. CE plans are discussed and agreed before the study begins, and reviewed as the study progresses. One area of increasing importance has been towards support to study FWs, with CAST team members advising study teams on the type and range of relevant supervision and on-the-job

training. My roles at the research centre have included supporting various CAST groups.

3.6.2 Field Workers at KEMRI-WT

Who are the fieldworkers (FWs)?

The largest group of staff employed at the KEMRI-WT are the "fieldworkers" (FWs). Field workers in the research centre have at least 12 years of formal education, with a minimum grade of C[18] and are often recruited from the study community, the KHDSS or Coast province.

What do they do?

The main responsibilities of fieldworkers include giving and collecting information. Some are trained to collect samples of body fluids such as blood, urine and mucus. Critically, they are often responsible for inviting community members to participate in research through informed consent processes.

Photo 3.8: A census FW riding to the field

FWs work in different research projects. One large team of FWs work in census, visiting all homes within the KHDSS area three times a year to collect information on residence, migration, births (including pregnancy histories) and deaths (Scott, Bauni et al. 2012). Photo 3.8 shows a KEMRI-WT census FW riding to field.

[18] According to Kenyan education system, O-level grade C qualifies for a diploma college but is below minimum entry level for a public (government) university.

Other fieldworkers support specific research projects. This may involve visiting homes within the community, being based at a government health centre or dispensaries or working from the hospital outpatient departments or inpatient wards. Some may work in more than one of these situations, for example, working on an inpatient ward and also following-up research participants at their own homes after discharge from the hospital. For some community-based studies, fieldworkers may be recruited from within the area where the study is based. This is to assist in easy access of the participants for studies, which require close monitoring of them, and to support employment of local community members. A small group of experienced fieldworkers are members of the Consent and Communication Committee (CCC) described above, (Boga, Davies et al. 2011). As members of the local community, and given fieldworkers' key role of interacting with local residents, their professional and social conduct and views are important to the way that the research centre is understood and perceived by the community.

Area of interest in fieldworkers' roles

Although the key role of FWs in the research programme and in studies is recognised, they clearly face significant challenges. Interviews with fieldworkers have shown that they share many of the (mis)understandings held by community members that are described above. This challenges their ability to respond to questions and issues raised within the community, and sometimes encourages inaccurate responses that could lead to further confusion and concerns (Gikonyo, Bejon et al. 2008). We have found that the more socially embedded FWs are in the community, the more insider knowledge they bring to conduct of the research. However, this can also present challenges including

unpopular actions of FWs jeopardizing the studies, or FWs being perceived as inadequately trained for some of their roles. These issues, I suggest, need to be taken seriously and appropriate levels and types of support provided to FWs.

To date, however, no study at the research centre has systematically explored fieldworkers' views about their roles, the range of issues they encounter in carrying out those roles and the systems, if any, they use to resolve these. Together with the gap in the literature described in 2.5, this contributed to my interest in carrying out this research. FWs' roles have implications for the quality of research data collected, and the ethical conduct of the research they are employed in.

3.7 Chapter conclusion

From this information on the study setting, there are three areas of importance for my research. Firstly, while there have been great strides in providing policy framework for research conduct in Kenya, these efforts are still fragmented across different line ministries, with much efforts still required by research institutions to pro-actively link up with relevant government bodies. This is important because research requires buy-in from key policy makers for translation to policies and for results benefits to reach relevant populations. The changing political and social landscape, including governance systems and ministerial positioning, are likely to affect the way research is conducted in Kenya; however, it is unclear in what form those changes will take and the implications for the research enterprise.

Secondly, the site of this research, the KEMRI-WT research programme, is a long-standing multi-disciplinary international collaborative research programme

headquartered in one of the poorest districts in the country. The centres' efforts to support ethical conduct of research in these environments have included a general awareness of the vulnerability of the vast majority of the population due to poverty and unmet health needs. Some of the programmes efforts, particularly boosting of health care services through collaboration with DHMT wherever possible, are aimed at providing an ethically supportive environment for research and at responding to the health needs of the populations.

Thirdly, the community generally views the work of KEMRI-WT positively based on a perception that it is a hospital that provides high quality health care. Previous studies showed little understanding of health research, existence of therapeutic misconceptions amongst some participants, and rumours and elements of mistrust with regards to KEMRI-WT research. This was attributed to unfamiliarity with research (its concepts and processes and how these differ from clinical practice), wealth and health inequalities between the research centre and community members. These factors also appeared to influence perceptions of appropriateness of informed consent for research.

Community engagement work at the research centre aimed at redressing some of these gaps, and at building and maintaining positive relationships with community members. One key group in interactions between the research centre and the community are FWs, employed for practical reasons such as access to and familiarity with participants, and knowledge of the local area, values and customs. Their role, at the interface of research implementation, is important because of the implications for quality of research data collected and the ethical conduct of research. However, few studies elsewhere, and none at the research centre, have systematically studied this group of staff.

Having justified the importance of this research (Chapter 2), and described the contextual background of the site of the research (Chapter 3), in the next chapter, I discuss the design of this research, the methods used and their justification, analysis of the data, and ethical aspects of my study.

CHAPTER 4 Research design and methodology

4.1 Introduction

As described in previous chapters, the main focus of this study is the nature and types of interactions between fieldworkers and research participants. Key areas of interest included types of research-related activities FWs were involved in, the challenges that FWs faced and if and how these were resolved. To provide information on these areas, I designed a descriptive primarily qualitative study with a quantitative component. In this chapter, I justify the selection of the research design and methods, describe data collection and analysis processes, and the limitations of the study.

The chapter is divided into 8 sections. After giving an overview of the research methodology (4.2), I describe the qualitative component of this research (4.3) and then the quantitative component (4.4). Even though the two methods were used complementarily, I describe them separately for clarity to the reader. I then describe processes I followed in data management and analysis (4.6), methodological strengths and weakness, including those related to my position, (4.7) and ethical considerations (4.8) for this research.

Trustworthiness in qualitative research refers to an assessment of the credibility of the entire research process (Patton 1999). The previous chapters described the justification and the context for this research, which are part of the criteria for assessing credibility and transferability of the findings to other contexts (Graneheim and Lundman 2004). This chapter provides further information on which credibility, transferability and dependability can be assessed (Graneheim and Lundman 2004; Ritchie and Lewis

2009). Influences of the researcher and how these shape the research process are part of the credibility criteria for qualitative research (Malterud 2001). In Chapter 1, I described my background and my interests in this research. I have deliberately taken an active voice throughout this thesis because I am an integral part of the process of the research, designing it, collecting the data, analysing, interpreting and writing it (Ritchie and Lewis 2009). I revisit my position in section 4.7 where I also discuss methodological strengths and weaknesses and how these feed into generalisability and credibility of the study.

4.2 The research design: Mixed methodology

The overall objective was: *to describe interactions between fieldworkers and study participants in a biomedical research setting in Africa, and the implications of these interactions for community engagement processes and ethics*. To address this main objective, six specific objectives were formulated (Table 4.1). A primarily qualitative study with a quantitative component was designed to address these objectives. A large component of the qualitative research was nested within two on-going community based studies.

Table 4.1 shows a summary of the methods used to explore the three objectives that formed the empirical part of this study, and the types of respondents that were involved. Objectives 4-6are addressed in the discussion chapter (Chapter 9).

Table 4.1: Study objectives and summary of research methods used

Specific objective	Method and number of participants
1. Develop an overview of who the fieldworkers are in KEMRI-WT, including their roles, overall expectations and concerns with their position in the institution.	• Formative phase of data collection: document review of HR information on FWs • 4 FGDs with 10 CLG members
	• The HH quantitative survey (see below)
2. Describe two key areas framing the interactions between FWs and participants in the case studies: household decision-making norms around research participation; and participants' hopes and anxieties 3. Describe the main challenges faced by FWs in their interactions with community members, if and how these were resolved	• Household quantitative survey of 362 HHs from 20 Enumeration Zones in KHDSS
	• Observation and follow-ups of fieldworkers in two selected case studies; 2 months of observation in case study A and 4 weeks in case study B
	• 6 FGDs with FWs (n=36 FWs) in the two case studies, and 1 in-depth interview (IDI) with 1 FW in case study B. • 2 IDIs with SFW (n=1) in case study A • 1 FGD with SFWs (n=5) in case study B • 5 IDIs with researchers in the two case studies (n=3).
	• 5 natural group discussions with participants (n=16) in case study A • 4 FGDs with participants (n=40) in case study B
4. Describe emerging dilemmas for FWs in their interactions with participants, including those associated with silent refusals, levels of benefits and the development of social relations. 5. Explore the implications of fieldworker and research participant interactions for research implementation and ethical practice. 6. Develop recommendations for supportive supervision of fieldworkers in this and other similar settings. *Addressed in chapter 9*	

Use of qualitative and quantitative methods in this research

Qualitative and quantitative research have been described as antithetical, as opposites of each other due to their different philosophical standpoints (Baum 1995; Huston and Rowan 1998). The philosophical orientation of quantitative research is premised on positivism, which assumes that every rationally justified assertion can be verified by

logic or mathematical proof, and that there is a stable reality, and a potential right way of understanding it (Baum 1995; Malterud 2001; Green and Thorogood 2007). The philosophical orientation of qualitative research is phenomenology that is, studying the meaning of a phenomenon (Pope and Mays 1995; Huston and Rowan 1998; Malterud 2001; Malterud 2001). It aims to help us in "the development of concepts which help us to understand social phenomenon in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences, and views of all the participants" (Pope and Mays 1995 p43). Qualitative research seeks answers to what, why and how questions that address how social experience is created and understood in everyday life, questions that do not always render themselves to quantitative methods (Huston and Rowan 1998; Bryman 2004).

Qualitative and quantitative research methods can be used together in several ways (Mays and Pope 1995; Malterud 2001; Patton 2002). Firstly, qualitative work can be conducted as an essential preliminary work before quantitative research to provide description and understanding of situations, and to identify/generate hypotheses, which can then be tested using quantitative research (Pope and Mays 1995; Huston and Rowan 1998; Bryman 2004). Secondly, qualitative research can be used to supplement quantitative work through for example triangulation, to give deeper understanding of quantitative data. Thirdly, qualitative research can build into quantitative research in those areas that are not amenable to quantitative methods, for example explore complex phenomena such as behaviours, attitudes and interactions (Mays and Pope 1995; Malterud 2001). In this research the two methodologies where used complementarily, with the quantitative component sandwiched between qualitative methods. Two main reasons which informed the design of the research in this way were:

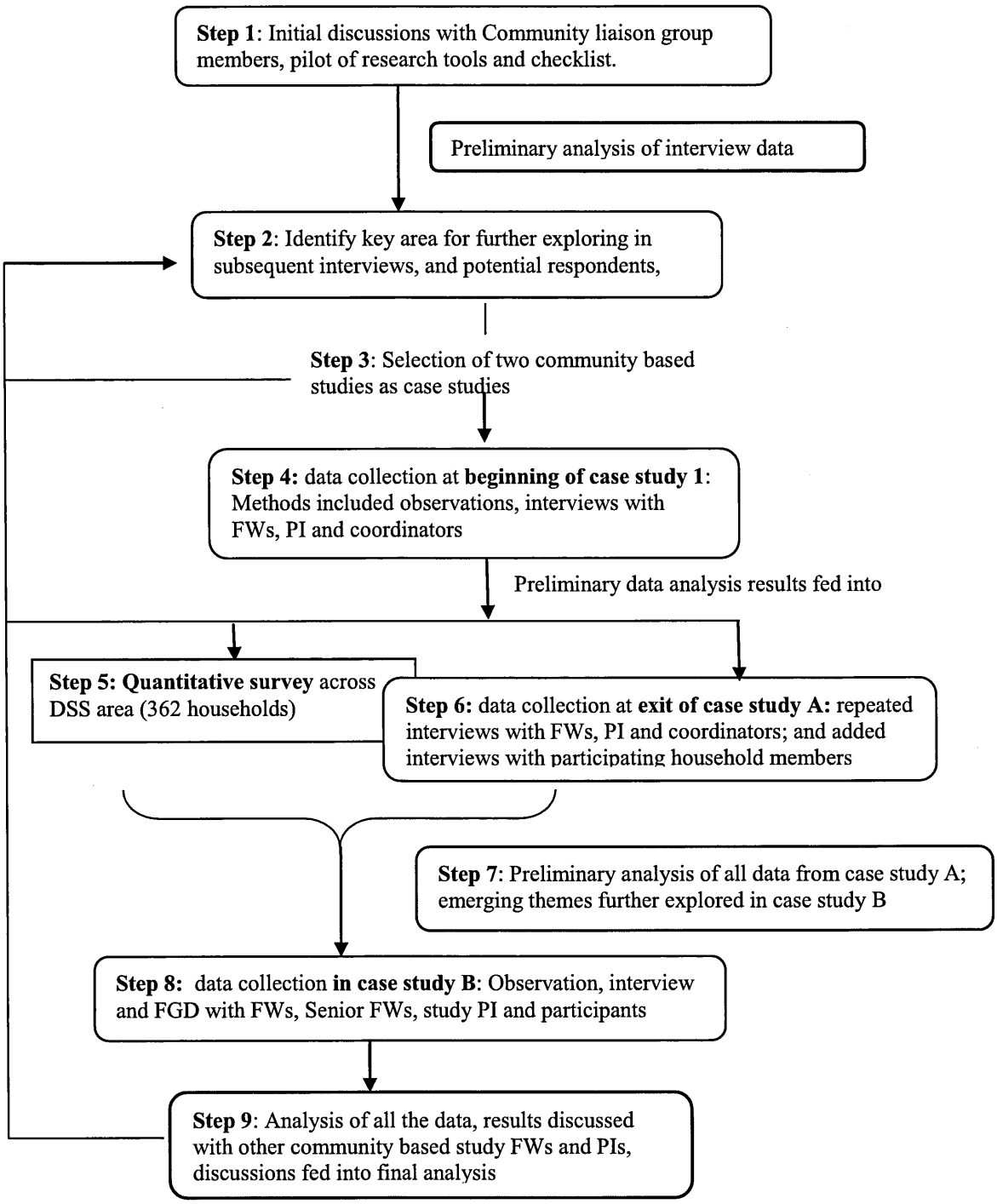
- to know how spread out or common some of the issues raised in qualitative interviews were among the KHDSS community,
- to provide depth and dimensions of the issues through qualitative methods.

I identified three main areas of focus for this research:

- *Contextual background information about FWs*: This included information on who the FWs at KEMRI-WT are, what their roles are, their views about those roles and of being employed at KEMRI-WT. A combination of methods was used including desk analysis of HR documents and interviews with CLG members and with FWs.
- *Challenges that FWs faced, how they were resolved and FWs roles in resolving them.* This component was explored qualitatively through observation and interviewing in two on-going community based studies.
- *Community members' views about FWs they interact with:* This component was explored using a variety of methods including a quantitative survey of nearly 400 households, and interviews with FWs and participants in on-going community based studies.

Figure 4.1 provides an overview of how the qualitative and quantitative methods used in this research complemented each other. The preliminary results of initial qualitative interviews fed into the design of the quantitative survey questions. Preliminary feedback of survey results helped refine areas that needed further exploration in subsequent qualitative data collection.

Figure 4.1: Summary of research methods used



4.3 Qualitative component

Qualitative research is aimed at learning from people's experiences. This includes making enquiries on meanings people make of their experiences, studying people in their social context and exploring phenomenon where there is not enough known about it (Patton 2002). Human interactions are a social phenomenon (Sofaer 1999), studying them therefore requires methodologies that allow exploration of different perspectives, meanings, opinions and observations of practice. Qualitative research methodologies, with their naturalistic orientation (Malterud 2001; Green and Thorogood 2007), were appropriate for this research. Seeking views and opinions across different respondents were aimed to add breadth to the information (that is the range of perspectives), while in-depth interviews were aimed add depth (Bryman 2004). The qualitative components of the research included formative research with community Liaison group (CLG) members, and qualitative methods nested within two community based studies (case studies). A key element of qualitative research is selection of the respondents, which I describe first.

Sampling for qualitative research:

Sampling in qualitative research differs fundamentally from quantitative sampling in that sample selection is conceptually driven, that is, either based on a theoretical framework that the research is based on or on the dimensions of a theory that the research is contributing to (Marshall 1996; Curtis, Gesler et al. 2000). Sampling therefore aims to ensure there is symbolic representation that is, "where the unit is chosen to 'represent' and 'symbolise' the features of relevance to investigation" (Ritchie and Lewis 2009 p84). The sample is also selected to ensure diversity, that is, to provide information on the full range of factors or features associated with the

phenomenon and to investigate the interdependency of variables so those most important can be disengaged from the less important ones. Because of the focus on depth of information, samples in qualitative research tend to be smaller than in quantitative research (Curtis, Gesler et al. 2000). To ensure breadth and depth, samples selected can include extreme (deviant) cases, typical cases, and/or maximum variation cases – that is, those which are as different as possible (Flick 2009).

Three main sampling methods used in qualitative research include purposive, convenience and theoretical approaches (Mays and Pope 1995; Pope and Mays 1995; Huston and Rowan 1998). Purposive sampling was my main strategy where groups or individuals are selected who can potentially provide the most relevant information about the phenomenon (Ritchie and Lewis 2009). Breadth and diversity of experiences and perspectives were explored thorough a) selecting different types of respondents (FWs, researchers, participants), and b) selecting different types of community based studies as case studies. There were two main stages of the study, the formative stage and the case study stage. The samples selected for each of the two stages are described in 4.3.3. I describe the two stages in turn.

4.3.1 Formative stage and tools development:

The formative stage of a qualitative research is a key step in identifying the range of issues and piloting the question guides, including assessing whether the questions are clear, consistent, and are valid for the enquiry (that is, that they elucidate the information they were meant to (Bryman 2004 p159-160). The formative phase enabled:

- development of an overview of the range, scope, depth and sensitivities of issues FWs encountered in interactions with participants;
- determination of the extent to which questions in the question guide were relevant to the key dimensions of the study; and
- counterchecking clarity of questions across different respondents.

I first interviewed members of CLG who occupy a unique position at the research centre by nature of their roles, as described in 3.6.1. By being intermediaries between the research centre, community, researchers, and FWs, CLG members have insights into multiple perspectives. All the eleven CLG members (community facilitators and FWs) come from Coast province, and most come from Kilifi County (see Table 4.2). All the senior FWs had been employed at KEMRI-WT for 6 years[19], while the average employment duration for community facilitators was 7.8 years.

Because seniority and levels of experience can influence quality of FGD (Green and Thorogood 2007), CLG members were divided into 2 groups; a group consisting of the SFWs and another of the facilitators and the CLM. Each group was interviewed twice; the first FGD aimed to elicit views about FWs at KEMRI-WT, and the second interview focused on challenges FWs face and how they are resolved. This formative phase fed into subsequent data collection processes.

[19] All the four SFWs in CLG were all employed at the same time.

Table 4.2: Socio-demographic characteristics of CLG members interviewed

Participant	Gender	Years at KEMRI-WT	Current role	Qualifications	Home locality
FW1	Male	6	Senior FW	O-level	Kilifi county
FW2	Male	6	Senior FW	O-level	Kilifi county
FW3	Female	6	Senior FW	O-level	Kilifi county
FW4	Female	6	Senior FW	O-level	Kilifi county
CF1	Male	16	Community facilitator	Post-graduate Diploma	Kilifi county
CF2	Male	12	Community facilitator	Diploma	Kilifi county
CF3	Male	1.5	Community Liaison Manager	Undergraduate	Kwale* County
CF4	Female	3	Community facilitator	Undergraduate	Kilifi county
CF5	Male	3	Community facilitator	Diploma	Kilifi county
Cf6	Male	3	Community facilitator	Undergraduate	Taveta* county
Cf7	Male	16	Community facilitator	Diploma	Kilifi county

*Both Kwale and Taveta counties are part of Coast Region

The second component of the qualitative research, which was the largest, used a case study approach, nested in two on-going community based studies (CBS), which I describe next.

4.3.2 Case studies: overview

Selection of case studies followed a two stage purposive sampling presented in Figure 4.1. The first stage involved selection of two community-based studies. The second stage involved selection of respondents in each case study.

Use of case study methodology for my qualitative research was to provide in-depth information and understanding of the nature of interactions between FWs and participants (Curtis, Gesler et al. 2000). Selection of cases is particularly important because *"...the case is the object of interest in its own right and the researcher aims to provide in depth elucidation of it"* (Bryman 2004 p50). Stakes, cited in Curtis (2000) distinguished between intrinsic cases, where a case is pre-specified as the focus of the research; and instrumental or collective casework where cases are chosen from possible alternatives in order to explore a research theme (Curtis, Gesler et al. 2000). The selection of the case studies in this research was instrumental in that I developed criteria, informed by the area of interest in this research, as described below.

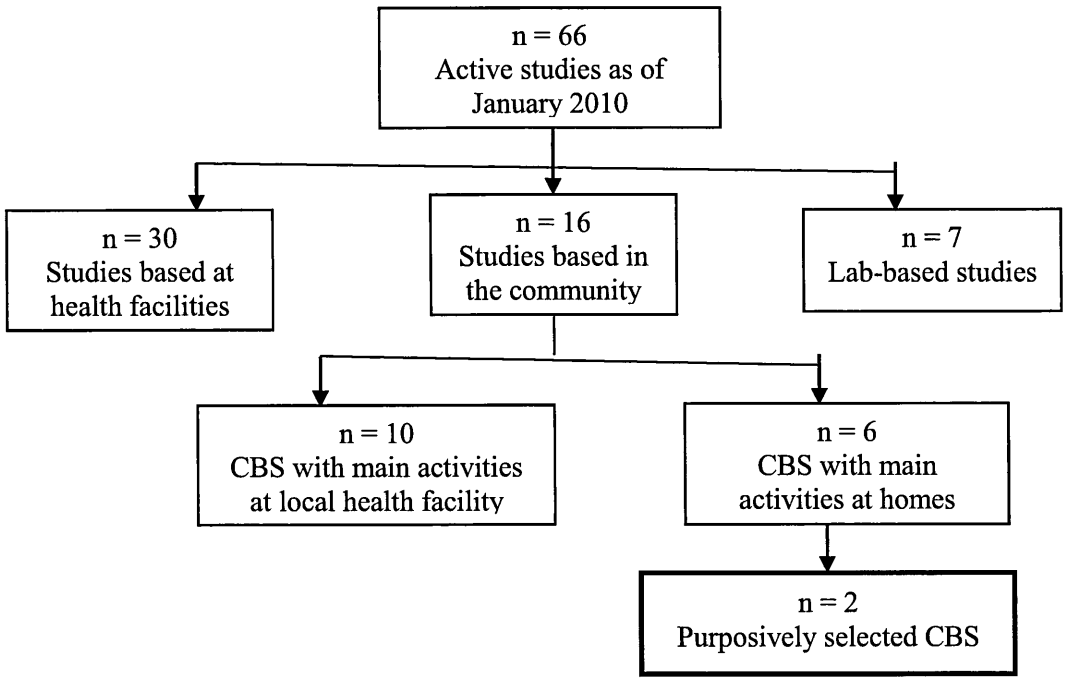
Table 4.3 presents the criteria I used to select the case studies in this research. The criteria was informed by the focus of my research, and therefore the interest was in selecting longitudinal studies with several FWs and extended interactions at the household level.

Of the 66 active studies in KEMRI-WT at the time (see Figure 4.2), 30 were based in health facilities, 16 were community-based studies (CBS) involving well people, and seven were lab-based studies. Of the 16 CBS, ten studies had most of the research activities happening at the local health facility with very few follow-up at homes while six had most research activities happening at participants' homes.

Table 4.3: Criteria for selecting case studies

Criteria	Justification
Number of fieldworkers:	Selected studies with more than one FW to be able to • cross check information across different respondents, minimise responder bias, that is, the tendency to respond desirably • explore FWs dynamics in a team
Where FWs were based	Studies with community-based FWs selected because: • enable exploration of how social embeddedness of FWs might influence research participation • FWs could easily identified by participants - as opposed to ward-based FWs who may be mistaken for doctors
Amount of interaction with participants	• selected on-going studies with considerable FW-participant interaction to minimise recall bias, and to learn nature of those interactions • studies involving different amounts of interactions; entire household, and individual participants, • studies at different stages of the research cycle as likely to affect nature of the interaction
Sensitivity of procedure or information and levels of benefits	• sensitivities around study procedures likely to impact on amount of time taken, range of issues FWs encountered, and nature of relationship between FWs and the participants • selected studies with different study procedures which are considered sensitive (e.g. included blood/nasal swabbing/vaccine)
Sampling framework for case study participants	• included studies with different types of study participants: community groups (e.g. households/families/populations clusters) and those of narrower groups (e.g. individuals)

Figure 4.2: Flow chart showing selection of community based case studies

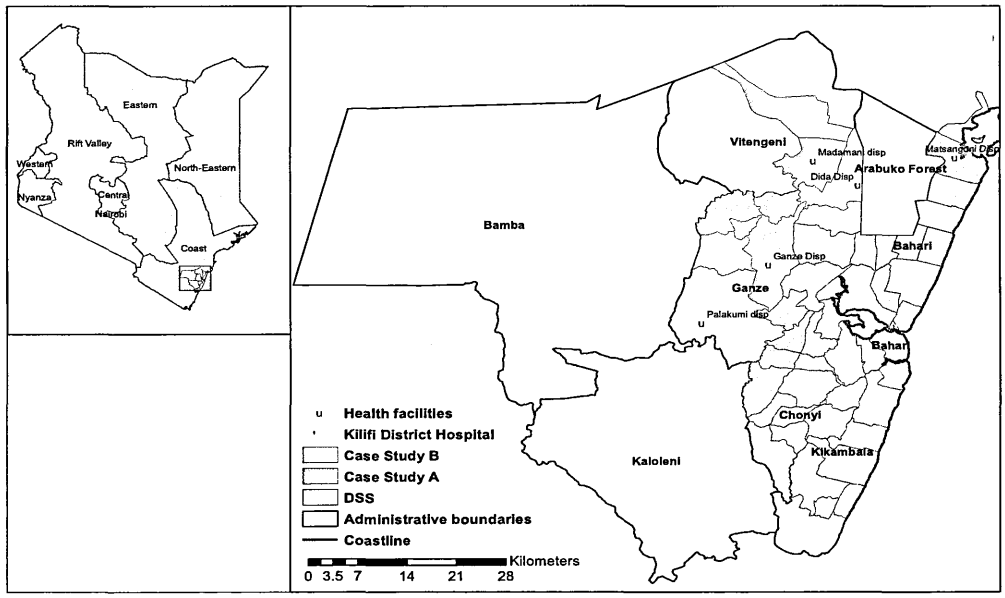


I purposely selected two studies from the six CBS using the criteria described above. The two studies were:

- an observational basic science studies involving entire household (target number of HH 50) looking at RSV transmission patterns in the household; referred to as case study A (CSA); and
- A malaria vaccine trial involving 900 children divided into two groups, 6-12 weeks and 5-17 months groups; referred to as case study B (CSB).

The two case studies where in geographically different localities, as shown in Figure 4.3. A summary of the key features of the two case studies is provided in Table 4.4. CSA is located within the KHDSS[20] while CSB is located outside the KHDSS, about 30 km from Kilifi District Hospital, and still within Kilifi County.

Figure 4.3: Map of Kilifi District showing the sites of the two case studies



[20] As described in KEMRI-WT, the research centre

Table 4.4: Key features of the two community based case studies

Feature	Case study A (RSV-HH study)	Case study B (a Malaria vaccine trial)
Study question/ objective	Who is infecting whom in the household with Respiratory Synctial Virus (RSV);	Evaluate the efficacy of a 'promising' malaria candidate vaccine against malaria disease in infants and children, and across diverse malaria transmission settings in Africa; • aimed to address key safety and efficacy information required for vaccine licensure;
Study design	Basic science descriptive study;	Double blind (observer blind), randomized, controlled, multi-centre study;
Study period	Oct 2009 – April 2010; participant involvement for 6 months;	2008 – 2013 (later extended to 2015); participants' involvement of 34 months;
Number of study sites	One site in KEMRI-WT, Kilifi;	Eleven sites in seven countries; Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and Tanzania
Ethical approvals	Local IRB, Kenyan National scientific and Ethical committees;	Local IRB, Kenya National ethical and scientific committees; Other review committees: included, Oxtrec (Oxford University), Joint Ethics Review Committee (by WHO), a Data Safety and Monitoring Board (DSMB) set up at each site, and for overall study;
Study area in Kilifi	One location, 15 kms from the Kilifi District Hospital (KDH), within KHDSS;	Three administrative divisions, 30 kms from KDH, 5 locations, in Kilifi County;
Composition of study team	16 team members; 10 FWs Of which 3 were CBAs[21], 2 data entry clerks, one each SFW, clinician, coordinator, PI and senior researcher; Team also included shared staff of lab technicians, drivers;	Minimum of 47 staff; 36 FWs, 3 SFWs, 3 clinicians, 2 Medical officers, and one each of study coordinator, PI and senior researcher; Team also included shared staff with other projects of data entry clerks, lab technicians, drivers;
Participants	Entire household in a defined locality; • with an infant born after previous RSV epidemic; and • at least one elder sibling to the infant; household defined as all members of a homestead who share at least one meal a day;	Children aged 6-12 weeks and 5-17 months at first vaccination; 16,000 children across the 11 sites, a minimum of 6,000 in each of the age category; For Kilifi site, allocated total of 900 children, 600 and 300 in the 5-17 months 6-12 weeks group respectively;
Study procedures	Follow-up visits at home every 3-4 days; data from each HH member collected at each visit included: • Temperature; • a nasopharyngeal flocked	Randomisation to one of three groups: • Experimental malaria vaccine and its booster at 1.5 years; • Experimental malaria vaccine and a different booster dose of either Meningitis and

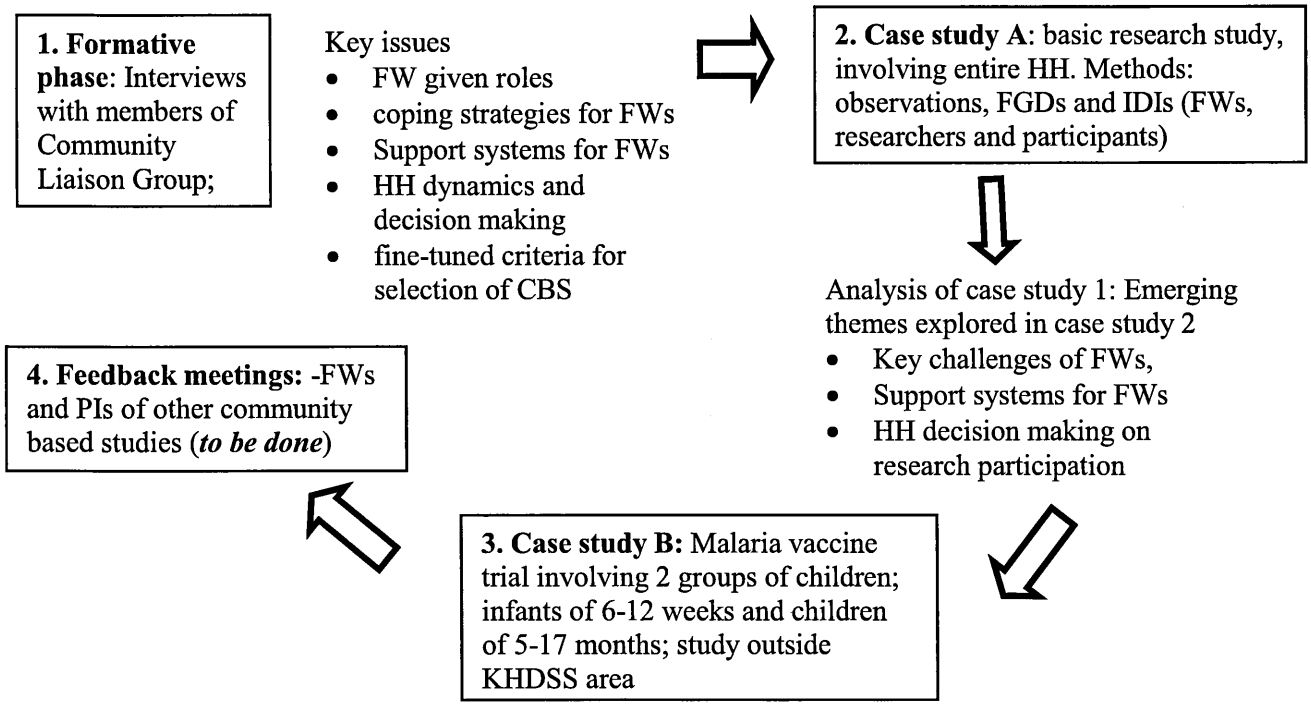
[21] CBA means Community Based Assistants, see 2.2.2.

	swab (NFS); • history of respiratory illness; • In addition, respiratory rate taken for all children under 5 years; Flocked oral swab (taken at alternate visits (once a week); A demographic and risk assessment questionnaire administered at beginning and end of the study;	septicaemia vaccine; and • three doses of rabies vaccine plus a different booster doses of Meningitis and septicaemia; *Procedures*: (see Appendix N) • Initial physical examination, medical history, anthropometric tests, temperature; • three vaccine doses each a month apart, and booster dose at 34 months; • 5 scheduled blood samples over 3 years; each 2.5mls; • Monitoring of minor and serious adverse; immediate and over time; • 6 consecutive follow-up visits post-vaccination days at home. Monitoring of minor and serious adverse events; • Referral to nearest health facility for illnesses, and to KDH for serious illnesses;
Risks	• Mild discomfort during NSF taking; • time inconveniences;	• Detailed side effects as is typical of vaccines trials provided in the study protocol and informed consent; • includes severe (such as convulsions, diarrhoea) and mild events (e.g. pain, swelling at vaccination site);
Benefits	For *participants:* • Free medical care for all common illnesses during study period; • clinical visits to every participating household once a month at home; • Other benefits/token staggered throughout the study period included two chairs to each household, sweets, educational materials and token[22] at end of study; *Community benefits:* • boosting local health services through provision of drugs, additional clinical staff; • water treatment for all communal water points; • provision of emergency medical aid during cholera epidemic including drugs, staff, referrals;	*For participants*: • Free health care for all conditions (chronic, acute, vaccine related or otherwise, injuries), throughout the study period (about 3 years). This includes: • Free referral for specialized treatment where required, all costs at government facilities covered while transport is provided for first visit to non-government facilities; • All transport to and from the hospital provided by the study team; • Meals provided for participant and accompanying parents/guardian for al clinic visits; *Communal benefits:* • Boosting of three health facilities where the study is based; renovation of existing buildings, providing equipments; boosting of health staff, provision of essential drugs, (see Table 4.4);

[22] Token given at the end of the study were said to be the study teams appreciation to participants for having persevered until the end of the study. They included educational materials, food items, clothes to family members.

In designing the way data were collected in the case studies, attention was given to the iterative process of sequential data collection, with preliminary analysis feeding into subsequent data collection. Figure 4.4 shows the iterative process of data collection and analysis followed in this research.

Figure 4.4: Iterative data collection process



4.3.3 Data collection methods in the qualitative component

Qualitative methods included observations, interviews and discussions with individuals and groups. A spectrum of formats for interviews range from structured to informal unstructured interviews (Green and Thorogood 2007). Informal interviews are similar to normal conversation with data collected almost opportunistically. The most commonly used method, the semi-structured interview with open questions is a compromise between the extremes, with the researcher setting the agenda and topics of

the interview and the interviewee's responses determining the kind of information that is produced (Bryman 2004; Green and Thorogood 2007). The iterative naturalistic approach of qualitative research means that data collection tools are developed, reviewed and altered as more data is collected and analysed (Marshall 1996). At each successive level of data collection and analysis, it is expected that emerging data supports or contradicts previous data in ways that are further explored.

The main methods used in this research where group and individual interviews, and observations, described next.

Observations

I conducted participant observations in both case studies. Observations aimed to provide first-hand information on the context under which FWs worked and the type and nature of interactions between FWs and households. At a secondary level, I used the opportunity of visiting households to identify potential households for later interviews, especially in case study A where I had greater time. Of the different types of observations (Mays and Pope 1995) - see Figure 4.5- I chose participant observation as the most appropriate for my fieldwork for several reasons. Firstly, I was already known by study researchers and FWs, as discussed in 4.7.1. Secondly, it was ethically justifiable, as part of showing respect for people's choice to be involved in my research, and to inform respondents of my role as a researcher. Thirdly, being part of the study team was a better way of experiencing and learning what goes on in interactions between FWs and participants.

Figure 4.5: Observational research roles (Mays and Pope 1995)

Complete Participant	Covert observation
Participant observation	Overt observation – mutual awareness of the research
Observer as participant	Essentially a one shot interview with no enduring relationship based on lengthy observation
Complete observer	Experimental design, no participation

My fieldwork included accompanying fieldworkers for household follow-ups and attending study-related meetings; I attended a total of 12 different meetings in case study A and 4 meetings in case study B. In case study A where I spent considerable amounts of time (nearly 4 months), I accompanied each of the initial 5 FW at least twice and visited 19 (out of 47 participating households) during this period. My follow-up visits with the other four FWs employed later were much shorter because the study was ending at the time. In both instances, a household follow-up lasted between 1-4 hours. During the household visit, I sometimes helped fieldworkers in filling various information sheets, engaged in informal chats with household members, and noted important points in my daily diary. I developed an observation guide for subsequent follow-up visits in both case studies (Appendix H).

Case study B covered a wider geographic area (see Figure 4.3) and had more fieldworkers and participants than case study A (see Table 4.4). In consultation with the study team (PI and FWs), we selected whom FWs I would accompany in the field ensuring diversity in activities. We selected fieldworkers who were giving study information to new participants, others who were following-up participants post-vaccination, following-up "difficult" participants, and FWs who were in geographically impassable areas (for example, hilly and/or far to reach areas). In total, I accompanied 9 out of 26 FWs in the study and visited 30 out of 160 participants over a period of one

month. The case study was in three geographically different localities, with each site served by a health facility. FWs and households for field visits were selected from each of the three sites. Each household visit lasted between 5-15 minutes with only one visit taking nearly 1 hour as the FW was giving consent information to a potential participant. I adapted the observation guide developed for case study A.

Focus group discussions (FGDs) and in-depth interviews (IDIs):

Interviews with groups of respondents included natural group discussions and focus group discussions. All individual interviews were in-depth interviews with those who seemed most conversant with the particular topic of interest (Green and Thorogood 2007).

Natural group discussions were held with adult household members all participating in case study A, because this approach was one way of exploring household decision-making dynamics (Green and Thorogood 2007). The advantage of natural group discussions is that members already know one another, and have established some norms of working as a group, which the research can get insights into. Because some of the topics I wanted to explore in these natural groups turned out to be sensitive, I used FGDs in subsequent interviews. In this way, I could explore general views around some of the gendered practices such as household decision-making dynamics (Bryman 2004 p349-360). Members of an FGD may have similar socio-demographic characteristic so as to elicit views in environments they feel free to; a situation that may be hampered if respondents have different levels of social-hierarchies, education, age demographics, or have different levels of experiences (Green and Thorogood 2007).

In total, I conducted 14 FGDs with 85 respondents, 5 natural group discussion with 16 respondent and 7 in-depth interviews with 4 different respondents (three of whom were interviewed twice). Table 4.5 shows summary of the type of interviews, and type and number of respondents interviewed in this research.

Table 4.5: Interviews conducted in the study

Interview type	Respondents
In-depth interviews	Case study A (PI, Study coordinator, Senior FW -each twice). Case study B: In-depth interview with one of the FWs
Natural group discussions	5 Natural group discussions with CSA participating households. (n=16)
Focus Group Discussions	2 FGDs with members of the community liaison group 3 FGDs with FWs in case study A (n=10) 8 FGDs with Field workers (n=40) (2 with CLG FWs, 3 with CSA FWs and 3 with CSB) 2 FGDs with Community liaison facilitators (n=6) 4 FGDs with CSB participants (grouped per gender) (n= 24) 1 FGD with SFW of CSB (n=5)

Selection of respondents for FGDs aimed to ensure maximum variation in views and perspectives (Bryman 2004). Since the area of focus was nature of interactions between FWs and participants there were two areas of sensitivity; a) household decision-making dynamics because of gender dynamics and inherent power relations b) discussion about FW roles which might have been perceived as if I was monitoring FW performance in ways that respondents may have felt uncomfortable with. In addition to changing methods (from natural group discussion to FGD), we selected respondent-households in case study A from the 19 households I previously spent considerable time with during my field observation work. In this way, I was not a total stranger and I had some idea of the dynamics of those households. Other ways we addressed these sensitivities are discussed in 4.7.

To ensure we explore diverse dimensions of research-related decision-making, we selected households with different living arrangements, and included:

- a united-extended and split-nuclear household,
- female-headed and male-headed households,
- difficult (withdrew) and easy- to-work-with household;

Through preliminary analysis of the data, and observations during interview, we realized that some women contributed minimally in the discussions and that they often tended to agree with husbands or elder families members, even when indicating otherwise non-verbally. Consequently, in case study B, instead of natural group discussions, we held FGDs with male and female respondents separately. Respondents were selected from each of the three health facilities where their children were attended to. Respondent from two health facilities were combined in FGD because the two sites were close together and participants used either health facilities interchangeably. We held 2 FGDs per site (one each with males and females) with parents of participating children. In selecting respondents, we first removed from our list 220 household that had been interviewed in another social science study that was going on at the time because some of our questions were similar, and to avoid bias arising from recalling research information discussed recently. Of the remaining 160 households, we selected respondents to explore diverse opinions, and included respondents who

- came from geographically different localities within the same study area;
- were followed-up by different FWs; and
- had different age-groups of children participating in the research that is, some had children in the 5-17 months category and the others had children in the 6-12 weeks category;

Given sensitivities around discussing refusals based on our previous experiences in case study A, we decided to include questions on refusals in the question guide (Appendix D), instead of holding FGD with research decliners.

Table 4.6 shows the chronology of qualitative methods used in this research, the objectives that were being explored in each phase of data collection, and the range of respondents involved.

Table 4.6: Objectives of discussions with different respondents

Respondents	Number of interviews	Objectives
Community Liaison group members; Community facilitators (n=7) and senior FWs (n=4)	4 FGDs, 2 each with CF and SFW groups	**1.** Explore the range of roles for different types of FWs at the research centre 2. Explore perceptions around nature of interactions between FWs and participants, in community-based studies, specifically: a. views on nature of interactions b. factors influencing nature of interactions and relationships c. challenges FWs face and how they are resolved d. support systems FWs draw on to address challenges **3.** Discuss nature of support of CLG to FWs, and to study teams
Field workers in case study A (n=10) and case study B (n=26)	6FGDs with 36 FWs; 3 FGDs in each case study	1. Discus the particular roles of FWs in the case study, at various stages of the study, if and how the roles have evolved over time, 2. Explore challenges FWs face in performing their roles, any challenges they encounter as a result of working for KEMRI, 3. Discuss how FWs cope with the challenges, the support systems they draw on, and why they use those systems, 4. Explore positive experiences FWs have encountered as a result of working for KEMRI-WT, and what has worked well in the studies, 5. Get views on some issues I observed in the field around, household decisions making, dynamics, silent refusals and study performance monitoring,
Senior FWs in CSA (n=1) and CSB (n=5)	1 IDI*in CSA and 1 FGD in CSB	1. Discuss what worked well in the study and challenges encountered 2. Explore the nature of FW roles and support systems that FWs draw on; and the roles of SFWs in providing support to FWs 3. To explore expectations that SFWs have of the FWs, and extent to which these are met
Study coordinator and study PI	4 IDIs, 2 each at start and exit of case study A.	1. Get general view around FW roles, if and how the roles changed in the course of the study 2. Explore challenges FWs faced, if and how resolved, 3. Discuss the support systems that were available to FWs, and extent to which they think they worked, 4. Discuss what worked well in the study, and the challenges they encountered,

		5. Explore views around the performance monitoring tools, and data quality checks,
participants in the two case studies; 16 in case study and 40 in case study B	5 natural group discussions (CSA) and 4 FGDs (CSB)	1. Explore perceptions of the study; what the study as about, how they got involved in the study, what they think about the study, 2. Explore participants opinions around how consent and retention decisions were made; what factors they considered, what processes they followed, who made the final decision and why, and FWs role if any in decision-making processes, 3. Get perceptions of being involved in the study, what challenges they face, what worked well and why, 4. Get views about silent refusals, what it is, why it happens, what the implication are and what the study team should do them, 5. Explore views around how FW performed their roles, what worked well, what did not, and what could have been done differently, 6. Get views on whether participants would be willing to participate in future KEMRI studies and y the basis for making such decisions

*Case study A had only 1 FW, hence could only hold an in-depth interview

4.4 Quantitative component

The questions for the quantitative component of this research were added to a planned post-intervention questionnaire for the evaluation of community engagement activities (see 3.6.1). In addition to saving on study costs and time, adding questions to the survey tool was appropriate because my questions were a sub-set of the community engagement strategy and some of the planned survey questionnaires were relevant to my research. The post-intervention survey tool, showing sections that were relevant for my research, is presented in Appendix J.

The quantitative evaluation of the community engagement strategy

As part of the overall evaluation of the research centre's communication strategy (3.6), a baseline survey was carried out in March to May 2005, and a repeat post-intervention survey planned and carried out in March 2010. The quantitative survey aimed to detect differences in knowledge and understanding of KEMRI-WT and its work at baseline and post-implementation of the communication strategy (Marsh, Kamuya et al. 2008). As a pre-post evaluation activity, the sample selected in 2005 was used in 2010. The sample size was calculated in 2005 to detect a 10% difference between pre- and post-intervention assuming that 30% respondents at baseline knew the role of KEMRI-WT as health research. Two-stage cluster sampling was followed at the time. The first involved selection of cluster in 3 urban and 17 rural Enumeration Zones (the clusters), which were randomly selected from 186 Enumeration Zones (EZ) in the KHDSS, each zone with nearly 140 households. The second stage of sampling involved selecting 20 households in each cluster, where the first household, the index household, was selected randomly using computer generated numbers and the neighbouring 20 households included in the survey. In total 400 households, 340 (75%) rural and 60

(15%) urban households, were selected for the baseline survey. 329 (82%) of the selected households were interviewed, of which 283 (82%) and 46 (18%) were from rural and urban and zones respectively. Of the 77 (18%) not interviewed, majority had out-migrated.

For the post-intervention survey in 2010, we included the original 400 households, and added 16 others to replace those that had out-migrated. Figure 4.6 shows a map of the KHDSS area and the households interviewed in each cluster sample for the 2010 survey. Of the total 364 households interviewed, 329 were interviewed at both baseline and post-intervention. Given that my research was descriptive, I used the same sample[23] calculated for the survey, and did not compare the 2005 and the 2010 data, since majority of my data were not included in the 2005 survey.

Survey on community views about FWs at KEMRI-WT

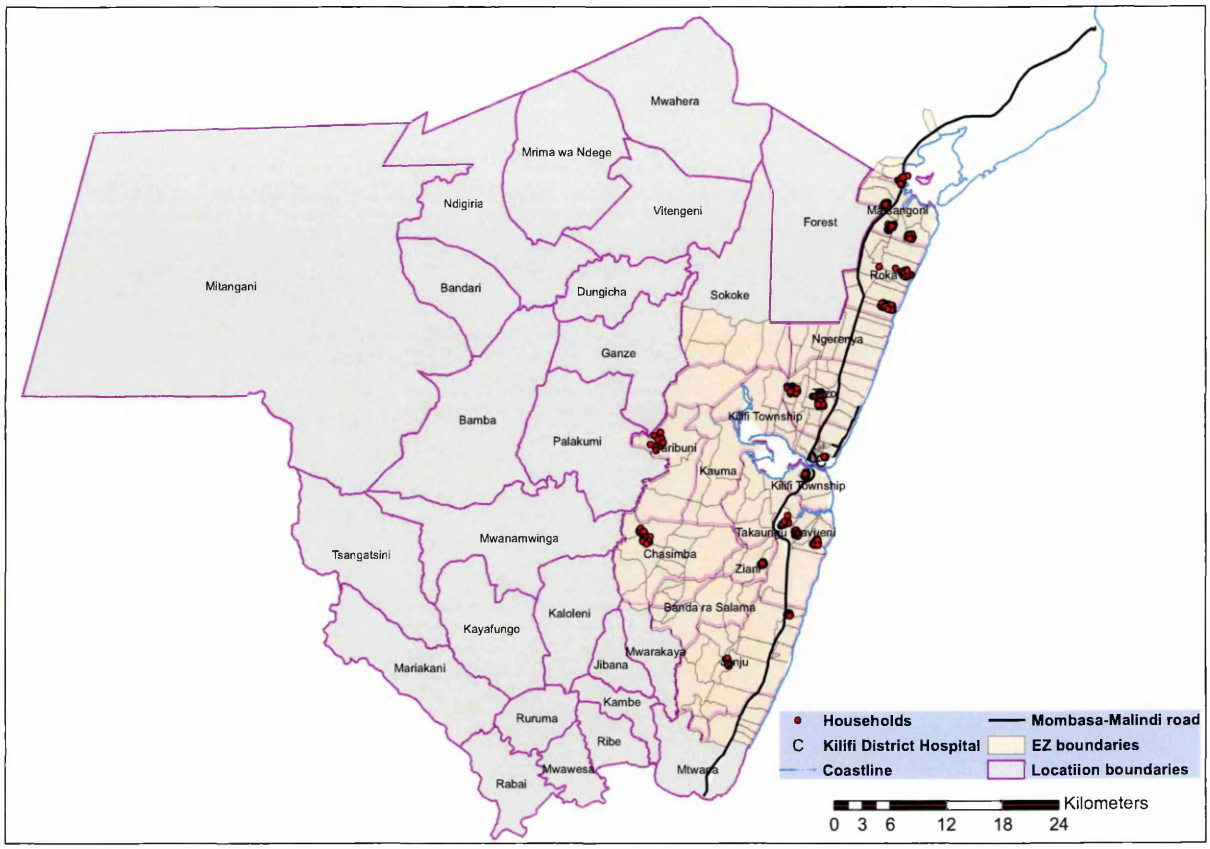
The aims of the survey questions for my research were two-fold:

1. develop an overview of KHDSS community members' perceptions of KEMRI-WT role, and of KEMRI-WT FWs.
2. find out whether regularity of FW visits to households in KHDSS was associated with better understanding of KEMRI-WT's role as conducting health research.

[23] The sample size required for my study would have been 307 respondents – if there had been no planned CE survey. The sample is calculated assuming that 15% $\pm$ 5% of those visited by a FW in previous six months reported some understanding of research; and that 70% of the KHDSS were visited by a FW in that period; with a significant criterion of 95%; and assuming a 10% loss to follow-up.

Using formula for sample size calculation of descriptive studies with outcome of interest expressed in proportion: N = {4 X (Z criterion)^2 X P (1-P)/D2; where N = sample size; Z value from table of 95% significant criterion = 1.96, P = proportion expected to understand research (15%) and D is the interval difference ($\pm$ 5%= 10). The calculation yielded 195 respondents; add 10% (n=20) loss to follow-up produces 215 respondents; which would be equivalent to 70% households assumed to have been visited by a FW. Computing for sample size (100% required) works out to 307 respondents. The sample size of 364 based on the household survey therefore provided more power for outcome estimation.

Figure 4.6: Map of households involved in the survey



The data for addressing the first aim of the survey was already included in the questionnaire as part of pre-post evaluation of the KEMRI-WT community engagement strategy. I added two sections in the questionnaire, *section 6* and *section 7* (see Appendix J) to provide information for aim two above, including,

- frequency and reasons for FWs visits at KHDSS homes in the previous 6 months[24] preceding the survey; and
- community members views in regards to trust

  Previous research conducted at the research centre showed that trust towards FWs and towards the research centre was often based on the health care services

[24] Given the KHDSS census between 3-4 months to cover all the households, six months seemed an appropriate time by which at least each household will have been visited by a KEMRI-WT FW.

provided (Gikonyo, Bejon et al. 2008). I used a likert scale to explore five dimensions of trust; interpersonal, competence, informational, institutional, and global/overall trust (Gilson 2003).

Despite criticism for use of a likert scale methodology in low-literacy populations (for example, that it takes too much time), it has been shown to elicit valuable data when used appropriately (Delavande, Gine et al. 2009). In my case, we considered it appropriate to provide a general overview information on community views towards KEMRI-WT FWs.

Piloting and pre-testing of the tools

Piloting can be compared to a 'dress-rehearsal' where the entire process of the survey is undertaken (Nyandieka, Bowden et al. 2002). In our case, piloting included all the stages that the moderator, and the survey team[25], were expected to undertake during actual survey including; identifying and tracing the household from KHDSS generated maps, carrying out the consent process, administering the questionnaire, and responding to questions. We piloted the survey in 22 households in two locations over 3 days[26]. We selected locations which neighbour those identified for the survey so the characteristics of the respondents in terms of exposure to KEMRI activities, would be similar (Bowden, Fox-Rushby et al. 2002). To avoid response bias from sharing information in the survey, we prioritized localities that neighbour those we piloted for

[25] The enumeration team consisted of 10 members: 6 enumerators, 3 observers including myself, and a driver. Each enumerator was expected to also note-taking (as the coded survey tool made it easier to do both). Enumerators were paired-up in the first two days of piloting, thereafter, each worked independently with observers rotating among the enumerators.

[26] The first day of piloting focused on pre-testing the new questions added to the baseline questionnaire; the baseline questionnaire was piloted and pre-tested at the time (in 2005). The other days were focused on piloting the whole survey process.

the survey. Through pre-testing of the questionnaire, we changed the 5-likert choices to three because it was difficult for participants to choose between agree and strongly agree, and disagree and strongly disagree.

We also included key messages, which were given at the end of the interview, in response to interviewees' questions about KEMRI-WT. Each session, including undertaking consent, took an average of 45 minutes. Each enumerator interviewed between 4-5 participants per day. To minimise bias due to information sharing among respondents, we planned to spend 1-2 days per enumeration zone. To increase likelihood of getting respondents at homes, we conducted interviews between 7am – 11am daily during the dry season of March 2010 when there were minimal farming activities.

Coding of quantitative survey data

We used the coding scheme developed at baseline survey, but added codes for the additional questions (see Appendix K for coding sheet) (Bowden, Fox-Rushby et al. 2002). The questionnaire coding was done by one research assistant (RA) and myself. We resolved differences by discussing among ourselves, referring to the original questionnaire and involving an independent[27] researcher where the first two approaches did not work. To get familiar with the coding scheme in order to ensure consistency, we randomly selected and coded 42 questionnaires together. We then each coded a further 25 questionnaires independently. For the remaining 224 questionnaires, the RA coded and flagged areas that needed to be resolved while I went through all the coded

[27] While the researcher is the PI for the wider survey study, she was independent in the sense that she was not involved in carrying out the survey, except as an advisor.

questionnaires, resolved anomalies, and involved the senior researcher where we both were not sure.

The information in the coded sheets was then entered into FoxPro, and cleaned by checking for anomalies and refereeing to initial questionnaire where necessarily. The data was then transferred into Stata Version 11.0, the statistical software I used for analysis.

4.5 Training of the interviewers and enumerators

The interview moderator should have appropriate skills and be conversant with the area of enquiry to elicit relevant information from respondents (Morrison-Beedy, Cote-Arsenault et al. 2001). Building rapport with respondents, use of topic guide, being able to observe and follow-up on non-verbal communication, and recognising when to use prompts in an interview are important skills in ensuring rich, quality data is collected. Awareness of these issues informed the selection and training of interviewers for my research.

I conducted all interviews in Kiswahili and/or English. Since I am not competent in Giriama language, I trained the four senior fieldworkers (2 females and 2 males) of the CLG (see 4.3.3) to conduct these interviews. The CLG SFWs have vast experiences, close to 6 years, of conducting interviews and surveys as their primary responsibilities. All the 4 SFWs come from Kilifi County, belong to Mijikenda tribes, are linguistically proficient in Giriama, Kiswahili, and English, have 12 years of schooling and know the study area. In addition, they are trained on communication skills, and in research ethics as part of their role in supporting community engagement activities at the research

centre; skills I drew on during the four days training prior to field work. The training programme and materials are included in (Appendix I). Through the training, we reviewed clarity and consistency of questions, translations (in Giriama and Kiswahili), and practised interview sessions with other staff of the CLG.

We held debrief sessions at the end of each day of interviews. We reviewed the question guides, discussed issues that emerged from the data, and the process of interviewing respondents, clarified areas that were difficult. The question guides used in the interviews are presented in Appendix D to Appendix G. We devised simple messages that were given prior to the informed consent (see Figure 4.7) to help clarify my study, and that it was once-off 2-hour discussion.

The same interviewers were also involved with the household surveys. In addition, 2 community facilitators where trained together with the 4 interviewers to enumerate for the survey. The training process is described in 4.4.

Figure 4.7: Seeking household permission

1. Thank you for the opportunity to discuss with you/your family. I would like to inform you of what is going to happen now.
2. I will explain to you about this study using this form (show consent form), and give you time to ask me questions.
3. Once I have answered all your questions, I will take you through the consent form, and ask permission to discuss with you. If you agree, I will request you to sign this consent form. The signing means that I have informed you of why I am here and you have given me permission to talk to you/the rest of household members.
4. I will then give you a copy of the consent form, and I will retain one signed copy.
5. Then we will start the discussion in which I will ask you questions. This discussion will take about 2 hours.
6. The end of this discussion will mark the end of your involvement in this research.

4.6 Data management and analysis

Qualitative data management

Where consent was provided, interviews were tape-recorded in addition to notes written down. Experienced data entry clerks[28], assisted by the note-takers and myself, transcribed the tapes using Ms Word version 2007. Where interviews were conducted in Kiswahili and Giriama, the notes were translated into English, and translations checked for consistency in meaning and language, with some key phrases retained in the original language. Interview tapes, transcripts, notebooks and electronic databases were stored at the research centre with access limited to those directly involved in this research, that is myself, supervisors, advisors, fieldworkers and data clerks directly involved in this project. Electronic records were password protected and codes used to anonymise respondents.

4.6.1 Data analysis

Qualitative data

I used inductive analysis primary guided by grounded theory in which data codes, concepts, and themes were generated from the raw data (Marcellus 2005). The iterative process of inductive analysis included overlapping stages of data management, development of descriptive and then explanatory accounts from the data (Bryman 2004; Ritchie and Lewis 2009). This process differs from deductive analysis in which the categories are pre-determined based on a theoretical framework (Ritchie and Lewis 2009).

[28] The clerks (three) are employed in the department, with data entry being their main responsibility. They all had over five years of experience of working in KEMRI-WT as data entry clerks

Data analysis started as soon as the first interviews were transcribed and cleaned, and continued throughout the study. All cleaned transcripts were uploaded into Nvivo Version 8.0, the software I used to organize and manage the data. I was previously trained and used the software extensively in my work. Immediately after each step of data collection, I printed and read the transcripts, familiarised myself with the data through line by line reading, identified emerging issues from each transcript, and made summaries. I chose the most informative FW FGD for initial open coding in Nvivo Version 8.0, as it would provide the most variable themes and categories (Ayres, Kavanaugh et al. 2003). Data under each open code were grouped into descriptive themes, and codes were merged, deleted and created as more transcripts were added (Ritchie and Lewis 2009). Through this process category titles became value-free, for example a direct code from the data, "unrealistic expectations from community members" changed to "community expectations" and 'unrealistic expectations' became a sub-code (see Appendix L for themes and codes identified through this process). The descriptive codes were further grouped into broader analytical themes.

An independent researcher was given part of the transcript notes, and diary notes to code. We compared the codes and themes we each developed independently and resolved differences by referring to the transcript. Through this iterative process of analysis, further areas of enquiry were identified. For each theme, charts were made across different respondents to compare perspectives.

Quantitative data

The quantitative survey data were entered and analyzed using Stata version 11.0. Summary statistics of proportions, distributions and measures of trend for key variables

were made. For example, questions 7, 8, 9 and 16 of the survey tool (Appendix J) aimed to investigate levels of understanding of research as main role of KEMRI-WT. We identified two levels of understanding research based on the coding scheme developed for definition of research.

- a 'clear' understanding of KEMRI-WT's role in which the respondent's answer corresponded with our key terms in the coding sheet;
- a 'somewhat' understanding of some of the key elements of research

In the analysis, I included both levels of understanding of research (that is, both clear and somewhat clear) given the recognised difficulties in accurate understanding of research.

I used univariate logistic regression to check for trends between frequency of FW visit, as a proxy for recent exposure to KEMRI activities, and understanding of research. I also checked for trend with possible confounders such as age, education level and support[29] for KEMRI-WT's work. For the likert scale calculations, I used frequencies and proportions for each question, and defined a cumulative score for all the questions as a proxy measure for whether or not the KHDSS community perceived FWs to be 'trustworthy'.

I used findings from the qualitative research to help explain the results of the quantitative results, and vice versa. Through this approach, I considered the use of the two methods as complementary and as part of triangulating the study findings aimed at strengthening credibility (internal validity) of the findings.

[29] Support to KEMRI was on a 5-choice likert question designed at baseline (and therefore could not be changed to 3-choice scale). It can be argued that understanding research could lead to better support or otherwise of KEMRI's activities. In this instance, in consultation with centre statistician and one of my supervisors, we made the decision to consider understanding as an outcome of level of support.

4.7 Strengths and weakness of the methodological approach

4.7.1 Reflexivity across the methodological process

> It is not possible for qualitative researchers to be totally objective, because total objectivity is not humanly possible. Each person's values are the results of a number of factors that include personality, socio-economic status, and culture (Ahern 1999 p407).

Reflexivity is about a researcher's iterative honest reflection of how their values, tacit knowledge, preconceptions, and interests may influence the social world they study (Cutcliffe 2003). While there is agreement that reflexivity is important in strengthening credibility of qualitative research, approaches to address it are contested. Some authors propose an active recognition of the centrality of the researcher's influences on the research process; the researcher being an object of study (Cutcliffe 2003). Others propose bracketing, that is putting aside, or controlling researchers influence, and place emphasise on being objective (Ahern 1999). Others advocate for a more explicit reflexive account to make the researcher accountable to the reader, and in so doing, enhance the credibility of the research (Cutcliffe 2003). In supporting the latter proposition, I started this thesis by describing my background (1.2) and the methodology and interpretative framework of this research, acknowledging that the outcome of this study is a process of co-learning and co-production (see 1.3 and 1.5). In this section, I discuss some of the ways my influences on the research might have been both strengths and limitations, and the way I responded to minimise the limitations.

Working within on-going research: A large part of this research consisted of working within on-going studies, as discussed in 4.3.2. Right from the beginning, I was aware of challenges which might arise with this approach. These included:

- staff members behaving differently because they knew they were being studied, the Hawthorne effect (McKnight, Des Jarlais et al. 2006);
- expectations from FWs that I could address issues they faced in the field, or forward these to their seniors;
- expectations from researchers that I would inform them of field issues that needed to be addressed, or of FWs 'misbehaving' in the field; and
- worries that case study participants may be less inclined to discuss with me, 'an outsider' about FWs, and may perceive me as a "study monitor"

The methodological discussions in 4.3.3 presented some of the ways we addressed these issues. These steps, I hope, helped to minimize the Hawthorne effect (McKnight, Des Jarlais et al. 2006). My extended stay in the case studies, participating in activities of the study team, helped me understand the studies better and the study teams to see me as one of their team members. Feedback and debriefing sessions with the study team helped address and clarify areas of concerns, and build some level of trust. We were also aware that we may not eliminate all issues about my positionality and that they formed an important part of this study.

Emotional distress: During my fieldwork, I sometimes encountered households in dire need of food aid and clothing, especially in case study A where there was drought. Sometimes I helped the households with small tokens, particularly some food items. Still, some situations were emotionally distressing, especially where I encountered

young children and infants crying for food, or there appeared to be no food available. I realised that my role was oscillating between being a 'disengaged researcher' and wanting to help where I can, and I ended up 'advocating' for more assistance from the research centre and from the specific studies. These issues made me so aware of the daily challenges and dilemmas FWs themselves faced, and I especially empathised with FWs and researchers when their requests for food aid were turned down (discussed in 9.3.2).

4.7.2 Using a mixed methods

Triangulation across methods helped explain some of the 'anomalies' observed in one method. For example, initial FGDs appeared to suggest that many households were unwelcoming of FWs, while quantitative survey findings showed that the majority of the respondents were supportive of FWs. Further exploration of this issue in subsequent interviews with FWs and participants in the two case studies showed that while, generally, community members were supportive of the FWs, there are several related factors that could influence acceptability of FWs including concerns around KEMRI-WT's work and rumours of association with devil worship practice. Using mixed methods approach enabled a deeper understanding of issues from a respondent's own description (qualitative) and an understanding of how spread out they were among the community (from quantitative data).

Triangulation of findings across different methods and respondents strengthened credibility (internal validity) of the research. For example, my field observations of FWs' dilemmas in handling silent refusals informed subsequent interviews with different respondents in the two case studies, as discussed in chapter 7.

4.7.3 Qualitative aspects

Longitudinal studies as case studies: Case studies, as described in 4.3.2, provided depth in understanding of the different dimensions of FWs roles and the nature of research interactions. The selection of the different case studies aimed at enhancing representational generalisation of the findings (Ritchie and Lewis 2009), that is, through triangulating across different respondents and case studies, the issues that emerged were likely to be reported in other studies in this setting. In addition, the description of context of the study in this chapter provides information for others to judge the extent to which the findings are generalisable to other settings. Some of the theoretical concepts that emerged from this research (discussed in 9.3) can further be explored as part of future research in other settings.

Inductive analysis: Inductive iterative process of analysis helped generate themes and codes informed by the data. Involving an independent researcher early on in the analysis, sharing subsequent analysis results with my supervisors, and feedback to case study teams helped to strength the credibility of the findings by bringing in multiple perspectives.

4.7.4 Quantitative aspects

Household survey: Large representative household surveys can provide information on causal relationships between variables and outcomes (Karamagi, Tumwine et al. 2006). The interest of the household survey in this study was not on causal relationships; rather it was on how widely spread-out some issues raised in the qualitative research

were among the community; for example, whether scepticism towards KEMRI-WT was as common as suggested in qualitative interviews. As discussed above, the two methods were used complementarily, and contributed to strengthen representational generalisability.

Likert scale: Use of the likert scale to measure trust in FWs was especially challenging methodologically; the analogous scale was not easily understood by the respondents. The initial pilot of the tool helped reduce the likert choices from five to three scales. It also became apparent that respondents were often giving explanations in addition to choosing a scale, or requested the enumerator to choose an option on the scale for them. In the end, the enumerator wrote the explanation as well as indicated the scale chosen. Our experience with likert scales suggests that they need to be carefully pre-tested, and that in some situations these are difficult to use as stand-alone tools.

4.8 Ethical considerations

This study was part of a wider study on evaluation of the implementation and the impact of the Programme's community engagement strategy, approved by the local and national science and ethics committees, described in 3.4 (see approval letter in Appendix B).

Ethics in practice

This study is grounded on ethics in practice. The experiences, views and relations I established with the study team helped me understand depths of their experiences, and to appreciate the strengths and dilemmas of working in the field. I also became aware

of the potential for positive relations to blur key ethical issues. For example, some team members were surprised when I sought their consent for interviews. Some said they trusted me and did not need to read the informed consent form. I still insisted on going through the consent information, as I felt it was the right thing to do; they needed to be aware of their rights, including the right to refuse to participate in my research.

In my research, I encountered three cases where interviewees were not keen to talk to the interviewers or me (see 7.3). All were community respondents, 2 in the household survey and 1 in a natural group discussion. Going through these experiences, albeit few, I appreciated the dilemmas for FWs in handling silent refusal.

Informed consent

All participants in this study gave consent to be involved in the study and signed the informed consent form (ICF) (see Appendix C for the various ICF used). Where household members participated as a unit, we explained the study to all members, sought permission and requested the household head to sign on their behalf. In cases where several nuclear families shared a household, consenting procedures followed those of the community-based study, to avoid confusion by introducing a different system.

Confidentiality

The area that seemed to cause worries for FWs about my research was in regards to confidentiality. Some FWs' were concerned that their bosses might get offended with some of their views, which could lead to reprimands or their contracts suspended. We discussed at length the methods of anonymization, and information to feedback to PIs.

FWs felt that I should present sensitive information as general views from the wider FW group, rather than assign it to FWs in a particular case study.

To ensure confidentiality for all respondents involved in this research, I used codes instead of names in all the transcripts and records, and tried as much as possible to remove all identifiers (see Abbreviations for codes in page xix). I stored tapes, transcripts and questionnaires in secured cabinets, and in password-protected computers. Access to these materials was limited only to those staff directly involved in this research.

Risks and benefits to participants and community

There were minimal anticipated risks in taking part to this study; interviews took a maximum of 2 hours. For interviews involving participants from the case studies, we followed the same compensation procedures as those of the study, as advised by the PIs. In CSA, where we interviewed participants in their homes, we did not give compensation since CSA was not compensating for follow-up visits. The PIs felt that since my study was embedded in their research, the study token and study benefits provided were enough; it would be difficult to introduce other compensations. For CSB we conducted interviews at a central place near the health facilities which participants attended used to attend for study visits. We provided transport, food and refreshments in line with CSB procedures. For staff interviews, we provided refreshments, in line with institutional guidance on compensation for time taken in study participation.

Community engagement strategy

This social science study, embedded within approved studies, operated within the frameworks of those studies, including with regards to community engagement processes. While we did not conduct extensive community engagement (as it was not necessary), I made sure that staff at the research centre and in the case study were aware that I was carrying out my research (see 4.3.3).

4.9 Chapter conclusion

In this chapter, I described the research design, the multiple approaches I used to collect the data (case studies, survey, observations, interviews), and the processes of data analysis. I described the strengths and limitations of this study and the approaches we used to address the limitations. In the next three chapters (Chapter 6-8), I present the empirical findings of this research. In the last chapter (Chapter 9), I discuss cross-cutting issues that emerge from the empirical findings, referencing to international literature.

Some terms used in these chapters are defined at the beginning of this thesis (see Translation of Swahili words) including the meaning of abbreviations used in participant quotes (see Abbreviations).

CHAPTER 5 Who are the fieldworkers at KEMRI-WT and what do they do?

5.1 Introduction

Whilst the focus of this research was the type and nature of interactions between fieldworkers (FWs) and study participants, these interactions happen within the context of the community that the FWs came from, resided within and performed their roles, and of the research institution that employed them. As described in the literature review, these institutions appear to influence FWs' motivation and ability to perform their roles. In this chapter, I begin to unravel the world of FWs at KEMRI-WT in more detail, to address objective 1: *To develop an overview of who the fieldworkers are in KEMRI-WT, including their roles, overall expectations and concerns with their position in the institution.* The chapter aims to provide background information about fieldworkers at the research centre, and the context in which they work.

I have divided the chapter into 3 main sections. I begin by describing who FWs are across the entire KEMRI-WT, the systems used to employ them, community liaison group members' perceptions of these systems and important influences of their work (5.2). Next, I present data on the FWs in the two case studies that were the focus of my qualitative work: how they were selected, their initial hopes and anxieties when they began their work, and a detailed description of their roles (5.3). Given the importance for FWs of community members' understanding of research and their views of FWs, I then present the quantitative data from the household survey to give a quantitative perspective on some of the issues raised in the other two sections (5.4).

The findings in this chapter are based on both the formative and main stages of research, on qualitative and quantitative methodologies, and on data received from the Human Resources (HR) department.

5.2 Overview of fieldworkers across the programme

At KEMRI-WT, 'fieldworkers'[30] refers to a cadre of staff whose roles include: generating maps; collecting, entering and cleaning data; giving research information; and carrying out simple non-invasive procedures such as collecting blood slides, and oral and nasal swabs. The FW group consists of diverse types of individuals as illustrated by the vignette at the beginning of this thesis (page 1) and below (Figure 5.1). While both vignettes illustrate the livelihood struggles for some of the FWs, FWs at the research have different background and interests; some come from slightly well off families; some FWs' main interests in the job is to advance their educational qualifications, while others aim to develop their communities. These diverse interests are not always communicated up front to PIs, but they are important in understanding factors that contribute to the way FWs perform their roles, as discussed in 9.3.

The FW group at KEMRI-WT consists of staff of different designations (job titles) including field assistants (FA), community based assistants (CBAs), fieldworkers (FWs)[31] and senior FWs (SFWs). The main distinction made at an institutional level is between FWs who are field or ward based, and those who are 'senior' or 'junior'. In

[30] The term fieldworkers was initially (at the start of the Programme) coined to refer to the field enumerators employed to collect census data, all of whom were local residents. Since then, the term has been used to refer to staff from the local population who are primarily employed to interact and collect data from local residents.

[31] These are also called 'junior' field workers, to differentiate from SFWs.

this thesis, I use the term fieldworker to refer to all of the above designations apart from the Senior FW (SFWs), unless stated otherwise

Figure 5.1: Illustrative case of a male FW

Muradali*[32] is a 37 year old man, with one wife and four children. He joined KEMRI-WT in 2010 as a FW employed on a clinical trial being conducted in his home village. None of his children were enrolled in the study as they were over the age limit for participation. He is one of the best performing FWs in the study according to the PIs, responsible for following up over 60 participants in the study.

Muradali is often asked by the study researchers to explain the study to participants who have many questions or who seem not to have understood it. *"My commitment to this work is not so much about the salary, but about seeing that I am doing something that is beneficial to the children here. The vaccine is already working, I am very happy I have made it possible for children here to get it..." he says.*

Muradali's commitment to the job is partly driven by a fear of losing it. Before joining the study, he worked in an office in Nairobi* but was laid off when the company closed. For several years he was unemployed and could not support his immediate or extended family. He decided to move his family from Nairobi city to his parents' rural home about 30kms from Kilifi town. He became a farmer, teaching his community about manure farming, and toiling in the farm all day to support his family. He had fall-outs with his siblings because he could not provide for them as well.

Gaining formal employment at KEMRI-WT has provided financial security for Muradali's immediate and extended family. He is keen to be retained in the organization for as long as possible. For him, working hard is much more than earning a good salary; it is about a commitment to help his community through the immediate and future benefits of the clinical trial, which he is already convinced works. He uses his social networks to reach out to participants.

[32] Name used is not the real name of the FW and the photo does not represent the person described in this vignette

5.2.1 How are FWs selected for employment at KEMRI-WT?

There are two main ways in which fieldworkers are employed at the research centre; an advertisement-based system, and reallocation at the end of contracts. Advertisements for FW posts are placed at strategic places such as chiefs' offices, and market places, and are publicised through public announcements. Shortlisted candidates are interviewed by an inter-department panel constituted by the Human Resource department in consultation with the researcher. Successful candidates undergo a probationary period of one to three months depending on the contract period offered.

At the end of a contract, a FW's contract can be terminated or extended through being deployed to new studies. A FW can also apply for another advertised post. A recommendation letter from the PI is required for those applying for an advertised post. In the past, there were no standardised criteria used to recommend extension or contract renewal for FWs. Much focus in the last three years has been to shift all job applications to an advertisement-based method.

Employing FWs from the KHDSS population was praised by CLG staff for providing employment opportunities for young people in the area; an illustration of the programme being responsive and sensitive to community needs. It was also described as being instrumental in ensuring a 'cohort of trusted' community members (FWs) were exposed to the programme and its research activities.

> "They say that they (KEMRI) are devil worshipping [but if] maybe your brother is the one working in KEMRI and you have not seen any devils, you get the courage that these are good people," (FW3, female, CLG/FGD01).

The *advertisement-based system* of employing FWs was praised for being transparent and fair to candidates, and for boosting morale and status of those employed.

> "... definitely if you attend an interview and you are picked a lot of the time people will appreciate 'well you did well'" (CF1, male, CLG/FGD02).

However, within this generally positive picture, there were concerns that some community members may not be aware of the system used to employ FWs, leading to a perception that the employment system is open to abuse (including taking of bribes), and that staff could influence who is employed in KEMRI-WT. It was felt that local administrative leaders (village elders and chiefs) could also influence who got employed because they were usually the first to be informed of FW posts and were sometimes required to write recommendation letters for prospective employees.

> "You know in this area people elect relatives, those who they know, there is *upendeleo* (discriminating others), by those who choose the ones to be employed...It's like the village elders who will say so and so (is chosen) ...and leave out other people who can also work and meet criteria (for employment)", (Pax5, female, CSB/FGD14).

Another concern was that emphasis on employment in areas with few employees had the potential to water-down qualifications as a main criterion for employment in favour of geographic distribution. This would discriminate against other more qualified tribes resident in other parts of KHDSS, as well as those who come from KHDSS but reside outside it. A related concern was that community members could demand employment from research institutions through threatening non-participation, and that widely advertising limited FW posts across the KHDSS locality risked creating expectations that could not be met, potentially contributing to dissatisfaction among the population.

"... so very soon you will not be surprised by having a community, say the Kauma community, saying we can't participate in a study unless you have employed one of our own because we know you have employed all over; yet they don't have someone who is qualified, and so what does the unit do in that scenario?" (CF1, male, CLG/FGD02).

"...maybe there are two [FW] posts advertised or one post advertised, then you are sending adverts to the 16 locations, then in the 16 locations each location sends fifty applications, and in all that process you want only one fieldworker. In the process, the other locations may see that this thing is not working... So some locations are complaining 'we don't have any one person because we want the most qualified person', but the most qualified person can come from Roka location which already has got a vast number of fieldworkers here" (FW2, male, CLG/FGD01).

This dissatisfaction could also generate negative attitudes towards FWs who do not come from a particular village – including those from a neighbouring village - and reluctance to enrol in research. Such reluctance was likely to be more pronounced where researchers had 'promised' or implied FW would be employed, but did not follow through.

A final concern raised in one FGD was that positive bias towards employment of Mijikenda tribes potentially creates an impression of 'a tribal research' outfit that is at odds with the image of an international research organisation, and possibly further fragments fragile relations across the different tribes resident within the district.

"In terms of the unit itself employing... from the KHDSS, I see it eventually having a negative impact in the sense that Kilifi is a small town and is becoming cosmopolitan... So, with time, people will start looking at KEMRI as a unit for the Giriama or Mijikenda [local tribes], because... people are aware that the policy is that KEMRI is employing (from the area)...so while it's a good thing,

especially for the community-based studies I think in the long run it may create a bit of a challenge in terms of, one, creating the image of KEMRI as belonging to a certain community, the Mijikenda and the rest (tribes) feeling that they are missing those opportunities; because if you want to develop those international standards, we need to balance between that and having staff who are employed competitively" (CF1, male, CLG/FGD02).

5.2.2 Number and distribution of FWs at the centre, and FW job grades

The Human Resource records showed that, as of November 2011, nearly a third (31.5%) of the 772 staff at the research centre were FWs (n=243)[33]. Table 5.1 shows the distribution of the FWs by gender across four characteristics: designation, workstation, qualification, and duration of employment at KEMRI-WT. Two of the indicators, qualification and duration of working for KEMRI-WT, are expected to influence job grade[34] (and therefore salary scale), as discussed below. Designation refers to official job title, which is indicative of some level of seniority; for example, a FW is senior to a field assistant (FA) and a community based assistant (CBA), and would be expected to be on a higher salary scale.

The majority of the 243 FWs were males (64.6%), were under the 'FW' designation (85.2%), and were based at the Kilifi workstation (87.7%). Most had 12 years of schooling (65%); and nearly half (48.8%) had worked for KEMRI-WT for less than 6 years; 4 (2%) had worked at KEMRI-WT for more than 21 years on rolling contracts.

[33] By the time of writing this report, the number of FWs had increased to 255. In this thesis, I use the initial data of 243 FWs.

[34] Refers to the research centre's system of placing a staff on a pay scale based on factors such as qualifications, experience and responsibility.

Table 5.1: Characteristics of FW at the research centre, by gender

Characteristic	Distribution by Gender Number, (%)		Total Number, (%)
	Female	Male	
Gender	86 (35.4)	157 (64.5)	243 (100)
Designation			
Community based Assistants	6 (2.5)	2 (0.8)	8 (3.3)
Field Assistants	8 (3.3)	2 (0.8)	10 (4.1)
Field workers	67 (27.5)	140 (57.6)	207 (85.2)
Senior FWs	5 (2.1)	13 (5.3)	18 (7.4)
Work station			
Kilifi	67 (27.6)	146 (60.1)	217 (87.7)
Malindi	9 (3.7)	5 (2.1)	15 (6.2)
Mombasa	4 (1.6)	3 (1.2)	7 (2.9)
Nairobi	4 (1.6)	4 (1.6)	6 (2.5)
Mtwapa	2 (0.8)	0	2 (0.8)
Highest level of education *(n=221)**			
Gender distribution	79 (35.7)	142 (64.3)	221
Undergraduate	0.....(0)	1 (0.5)	1 (0.4
Diploma	9 (4.1)	18 (8.1)	27 (11.1)
A-Level	0 (0)	1 (0.5)	1 (0.4)
Certificate	8 (3.6)	14 (6.3)	22 (9.1)
O-Level	53 (24.0)	105 (47.5)	158 (65)
Primary class eight (8 years)	9 (4.1)	3 (1.4)	12 (4.9)
Duration of employment at KEMRI-WT in years *(n=201)*:**			
Gender distribution	67 (33.3)	134 (33.3)	201 (82.7)
1-5 years	20 (10.0)	78 (38.8)	98 (48.4)
6-10 years	26 (12.9)	29 (14.4)	55 (27.4)
11-15 years	14 (7.0)	21 (10.4)	35 (17.4)
16-20 years	4 (2.0)	5 (2.5)	9 (3.45)
≥21 years	3 (1.5)	1 (0.5)	4 (2)

* Data were missing for 22 FWs; 7 female and 15 male.
** Data were missing for 42 FWs; 9 female and 23 male.

Figures 5.2 to 5.4 show FW characteristics by gender. The data show proportionally more male than female FWs at higher job designations of FWs and SFWs (Figure 5.2). Males also have higher levels of education (Figure 5.3), longer durations of employment at KEMRI-WT (Figure 5.4), and higher job grades (Figure 5.5). One

reason for fewer female FWs is that fewer girls than boys attain 12 years of schooling in this region and fewer still attain the mean grade of C, the main qualification criteria for a FW position. In addition, some of the job requirements such as riding motorbikes, bicycles, and working late hours tend to be discriminative against female FWs, and there are safety arguments for not employing female FWs in some localities. This is an area requiring careful consideration because of the gendered nature of interactions at household level between FWs and participants, as described in (8.4).

Figure 5.2: FW distribution by gender and designation

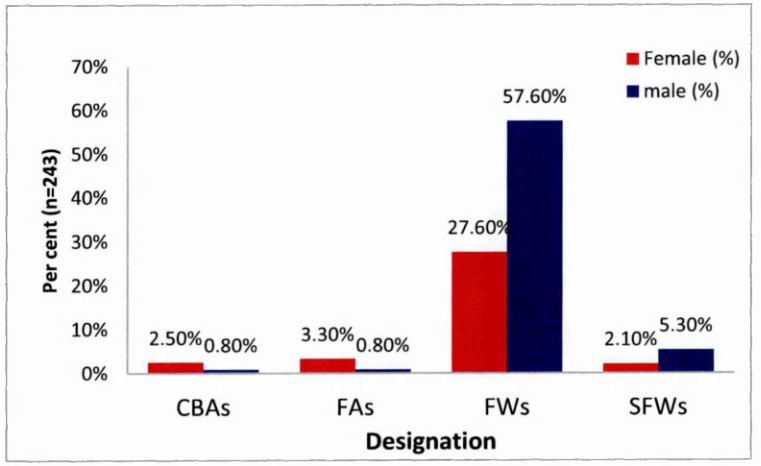


Figure 5.3: FW distribution by gender and education level

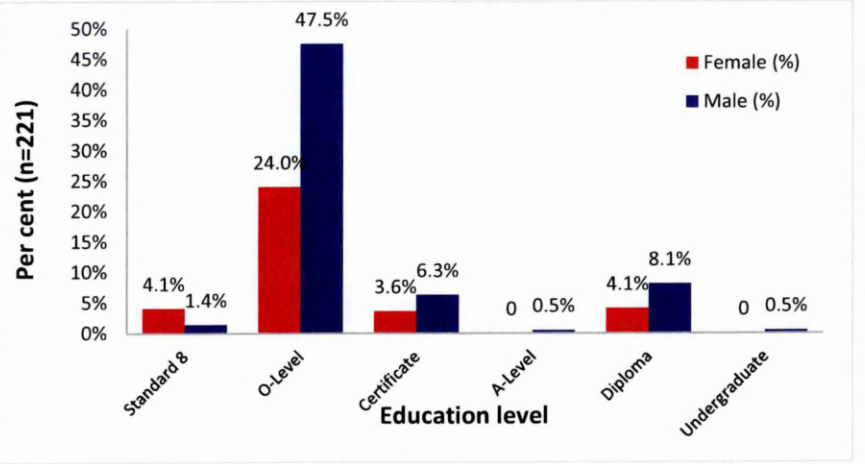


Figure 5.4: FW distribution by gender and work duration

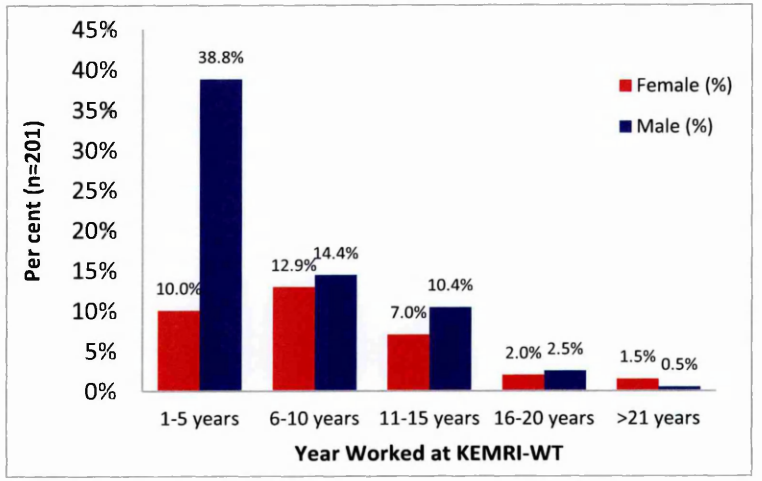
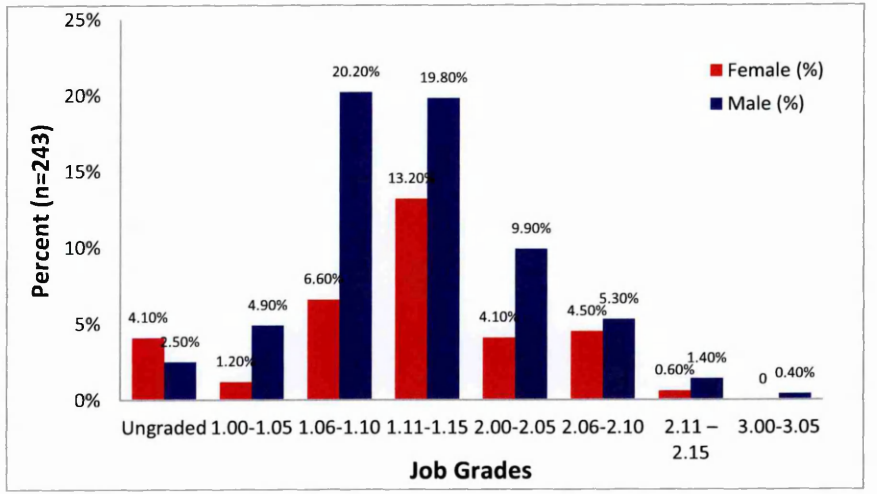


Figure 5.5: FW distribution by gender and job-grade



At the research centre, job grades determine salary scale; a higher job grade is reflective of increased responsibility, higher education level and higher performance. The job grades for local staff[35] range from 1.00 with a monthly salary equivalent of $212[36] to 8.15 with a monthly salary equivalent of $8,453[37] (for example, for a senior researcher or a centre director). International staff salary scales are not publicly available within the KEMRI-WT programme; they are however available in the international institutions the staff are employed in. Salary level is an issue of concern, contributing to a recent re-grading of all jobs, as discussed further below.

Job grades and salary scales for FWs at the time of collecting the data are presented in Table 5.2. Nearly 60% of the 243 FWs were in job groups 1.06-1.15, with a monthly salary equivalent of USD 252-344[38]. Ten of the staff (6.6%) were categorised as ungraded as they were 'volunteer[39]' casual workers with less than the minimum qualification for FW post and were paid a monthly salary equivalent of $188[40]. A new FW's starting salary of $212 is 22.5% higher than that of a trained primary school teacher with 12 years of schooling and a college certificate for teacher training, who would earn Ksh.13,800 per month ($173) (http://www.tsc.go.ke/). Nevertheless, it should be recognised that low staff remuneration has contributed to recent labour strikes among public sector teachers and health staff (doctors, nurses, and clinical officer)[41].

[35] Local staff refers to staff (including FWs) whose jobs are advertised within the country.
[36] Using exchange rate of 1USD ($) = Ksh.80 as of November 2011, time the data as collected.
[37] No one in the Programme is at this level, it exists to provide room for growth over the years.
[38] Exchange rate of 1USD ($) = Ksh.80 as of 2011, at the time of data collection
[39] The community members started as volunteers in a community action research project aimed at eliminating mosquito habitats; were later formally recognized as casual employees
[40] After the 2012 job review, the *ungraded* cadre of staff were upgraded a into the wider FW group
[41] By the time of submitting thesis, teachers had been on a 3-week labour strike that lead to renegotiating of salaries with the Kenyan Government; however the final agreements were not public at the time of writing.

Table 5.2: Job grade and salary scales for FW at KEMRI-WT

Job grade	Distribution by Gender Number (%)		Salary scale (Ksh.)[42]	Salary scale USD ($)[43]	Number of FWs (%)
	Female	**Male**			
Ungraded	10 (4.1)	6 (2.5)	15,000	187.5	16 (6.6)
1.00-1.05	3 (1.2)	12 (4.9)	16,985 - 19,491	212.3 - 243.6	15 (6.2)
1.06-1.10	16 (6.6)	49 (20.2)	20,173 - 23,150	252.2 - 289.4	65 (26.8)
1.11-1.15	32 (13.2)	48 (19.8)	23,595 - 27,494	294.9 - 343.7	80 (32.9)
2.00-2.05	10 (4.1)	24 (9.9)	25,666 -2 9,452	320.8 - 368.2	34 (14.0)
2.06-2.10	11 (4.5)	13 (5.3)	30,484 - 34,980	381.1 - 437.3	24 (9.9)
2.11-2.15	4 (0.6)	4 (1.4)	36,205 - 41,545	452.6 - 519.3	8 (3.3)
3.00-3.05	0	1 (0.4)	38,783 - 44,504	484.8 - 556.3	1 (0.4)

* Each grade band has 15 grade points. The lowest job grade at the centre is 1.00, the highest (for senior research follows). The job-grade refers to locally (Kenyan and east African) employees.

In addition to the above system of grading staff, FWs also appeared to have an informal system of assigning grades and seniority within their cadre, based on observation of each other's roles and perceived closeness with the PI. For example, there appeared to be a perception that ward and office-based FWs were more senior than field-based FWs because they tended to distribute work to those going to the field, had better working environments (air-conditioned rooms, computers and desk space), and were perceived to easily access the PIs. As with PIs, they also did not wear KEMRI-WT T-shirts.

> "Yea, there is a perception that, those that goes to the field, they are (*laughter*) juniors than those that are in the office. And it is taken that maybe those that go to the field have been you know... given the work to go do by those that are in the office, so there is that perception that if you are not going to the field, then you are 'Patel' (senior)" (FW1, male, CLG/FGD03)

To FWs, perceived seniority mattered beyond salary; it consolidated their status among their peers and in the KHDSS community they worked in. Fieldworkers reported that

[42] As of 1st November 2011 at the time of collecting the data
[43] Exchange rate of 1USD ($) = Ksh.80 as of 2011

community members had similar views in regards to perceived seniority. These issues highlight concerns and the extent to which institutional systems are open and transparent.

5.2.3 Important influences on how FWs do their work

In interviews, three areas emerged that potentially influence how FWs view their roles and position in the research centre, and which can potentially influence how they perform their roles. These include factors related to how FWs perceive they are valued and recognised at the research centre; views on fairness and transparency of systems used to promote staff; and perceptions and reputation of KEMRI and its staff among the community. I discuss these in turn.

How valued are FWs within the overall institution?

Generally, staff described FWs as having key roles in doing the core business of the research centre, particularly collecting data that informs research findings. They also described some of the difficult circumstances in which FWs undertake their roles including; large amount of work involved (*'running up and down in the field')* and the conditions under which they work (*'working under the hot sun'; 'collecting data whether it's raining or hot'; 'going up and down the valleys looking for households'*...). Pressure is exacerbated by *'having to meet the targets for the day'.*

Some staff felt that FWs' contribution to research, while important, is usually not recognized; for example being at lower job cadres, being paid lower salaries than drivers, and having few resources such as computers and office space than others:

> "...a fieldworker is a person who is assigned to collect data from the field, but according to KEMRI, fieldworkers...[are] the lowest level employees who collect data in the field" (FW3, female, CLG/FGD01).

At the time of doing the interviews, *there was a concern about a lack of transparency in FW promotion, and contract extensions.* Firstly, there was a concern that many fieldworkers stay in the same job grade for many years.

> "Most of the time our fellow FWs ... have been complaining, they feel they have vast experience and yet those who have come recently are promoted, and others who have been here for a long time, and they think they have been doing a good job, are not promoted, so it's not clear" (FW1, male CLG/FGD02).

Secondly, there was dissatisfaction with perceived unfairness or lack of transparency in FW promotions and contract extensions. Principal Investigators (PIs) were perceived to influence promotion of FWs using unclear criteria, and there were some concerns that FWs promoted in this way were undermined by colleagues.

> "...these people (FWs) have been together for some time and...one [FW] moves up and others...those who have not moved will feel like something unfair happened... so when there is extra work to be done, they leave it to the one who has been promoted, after all they have just been promoted..." (CF6, male, CLG/FGD02).

Concerns across the research programme with salary scales, job grades and promotions systems contributed to an extensive salary and job review carried out in 2011/2012. One of the results was a new job grade scale and salary scheme for all staff cadres, and increases in salaries of between 6- 40% backdated to February 2012. Other changes included standardized staff appraisal systems, annual target setting for staff, and setting up employee representative forums. A special committee has been set up to design and advise on FW career progression pathway.

Perceptions and reputation of KEMRI-WT and of its staff

Positive views of the research centre documented in previous studies (see 3.6) appeared to extend to FWs, who are sometimes referred to as doctors because of their work of giving 'health' information at consent, and of collecting health-related data and samples from participants:

> "Sometimes fieldworkers are mistaken as doctors during consenting (as they) give information about vaccine side effects. In some studies fieldworkers are given such drugs like paracetamols to give as first aid to children they find with fevers. Therefore, when the mothers see that this FW has checked the temperature of the child and has given them drugs ... then the mother says that he (FW) is a doctor" (CF2, male, CLG/FGD02).

These positive views of KEMRI-WT and FWs reportedly facilitated FWs to be welcomed into people's homes, and to be respected for working in a reputable organization.

Staff also reported that community members have numerous misperceptions of the research centre, and of its activities, in similar ways to those documented in previous studies (see 3.6). Concern reiterated included those related to amount and use of blood samples, sources of KEMRI-WT wealth, and of associating KEMRI-WT with devil worship activities.

> "...although you have explained [the sources of funds], they still ask 'but how sure are you that those funds are not from devil worshiping organization or devil worshiping sources?'" (CF7, male, CLG/FGD02).

The snake in the KEMRI-WT logo and 'unexplained' deaths of its staff are other indicators used to support descriptions of KEMRI-WT as a devil worship organization. The issue with devil worship for FWs is that it presents significant challenges in being

accepted, or even listened to, in those households where members believe it or are sceptical of KEMRI-WT's work.

> "Some of the people don't want to hear about KEMRI. When you are at the gate and you say you are from KEMRI, and before you have even said why you have come to their home, they tell you to go back, they don't want to hear anything about KEMRI" (FW3, female, CLG/FGD01)

Further complicating the roles for FWs is that by providing information about KEMRI-WT's work in order to dispel rumours, FWs are sometimes perceived to be lying, or to have been inducted into devil worship, and thus defending it.

Research on taboo or locally sensitive topics was another area of concern for FWs visiting participants' at their homes. HIV research on Men who have sex with Men (MSM) heightened safety concerns for FWs. Some of the public anti-gay demonstrations targeted KEMRI-WT field offices, staff and participants in HIV research. KEMRI-WT was perceived to be promoting homosexuality. In interviews, staff described being afraid to be associated with KEMRI-WT; they were mocked and segregated by friends and peers, and sometimes had to publicly explain their sexual orientation. Where staff tried to explain the importance of the research, they were seen as defending unpopular practices for the sake of safeguarding their jobs.

> "...So during that time, people were saying 'these KEMRI people are bringing MSMs from Malindi to work them out here, they are bringing bad behaviour in our area'. So we, KEMRI staff were really harassed. Whenever I passed somewhere, people would say things like 'these are the guys who are working with the MSMs' and it was bad, not just for FWs but for all KEMRI staff.... I was at a joint one time taking a soda...Everybody was involved in the discussion, and they were laughing at us, Arrgghh!" (FW2, male CLG/FGD03)

Another concern raised in staff interviews was the marred reputation of male FWs due to rumours of some of them engaging in extra-marital relations with some married women in the community. An incident that happened nearly ten years ago, in which the male FW was beaten up by the woman's husband and his friend, was narrated in all staff interviews. One staff member described the feeling at the time:

> "... I was working in the field at the time, it was like everywhere you went people were complaining that this KEMRI people are misbehaving, they are having affairs with peoples' wives in the community; so it was a really big thing ... it really took time before things settled down. ...It did affect to a very large extend the work of KEMRI because the behaviour of that fieldworker was not looked at from an individual point of view but rather as that of the programme at large and the people who work here, especially those who work in the field. So a lot of people thought all those people who work in the field have that same behaviour, and so the trust that people had towards people in the field was affected to a great extend..." (CF1, male CLG/FGD04).

Staff also felt that community members seemed to forget rather quickly similar incidents where staff were fired on suspicion of engaging in extra-marital affairs. The suspicions of extra-marital affairs were attributed to jealousness from husbands who lived away from their wives. Other suspicions were described as a couple's strategy to extort monetary compensation from the male FW, a practise popularly known as "*malu*"[44].

> "A CBA was moved from the community to work in the offices... and from him he said he was moved because there were mothers who asked him to sleep with them and he did not want... (FW4, female, CLG/FGD01).

> "[On an incident where a woman tried to seduce a male FW]...but the fieldworker is very genuine he doesn't know what is happening, he has warned

[44] the compensation for adultery with a man's wife or daughter' Parkin, D. J. (1991). Sacrod Void: Spatial images of Work and Ritual Among Giriama of kenya. Cambridge, Cambridge University Press.

that lady several times (to stop seducing him) but she keeps calling him (on phone)...so the issue has been reported to the study team...one of the resolutions is for the FW to change his [phone] line..." (CF4, female, CLG/FGD02).

These views of the research centre have several implications for FWs. The positive reputation of KEMRI-WT as a 'hospital' may make FWs more acceptable in the community; but this is based on misperceptions of who FWs are (*doctors*) what they do (*provide treatment*). While FWs sometimes appreciate the attention this gives them, it can also lead to difficulties in explaining their research work, an activity often conflated with health care. The negative images of KEMRI-WT might make the work of FWs much harder as the community may not easily trust them. These issues are further discussed in 8.4.2.

Having presented overall figures and views about FWs at the research centre, I now describe the FWs employed in the two case studies, their perceptions of being employed, and the formal roles they were given. Later, I describe the views of KDHSS community members towards KEMRI-WT and FWs, based on data from the household survey.

5.3 Fieldworkers in the case studies: selection, initial hopes and anxieties

The main qualitative work of this research was nested in two community-based case studies described in detail in 4.3. The first case study (case study A - CSA) was an observational basic science study involving 47 entire households in one location within the KHDSS community. The second case study (case study B - CSB) was a multi-site double blind randomized malaria vaccine trial involving nearly 900 children, grouped

into two age-groups; 300 children of 6-12 weeks and 600 children of 5-17 months (see Table 4.4 for details of the case studies). In this section, I describe the social-demographic characteristics of the FWs employed in the two case studies, their initial hopes and anxieties, and later, the formal roles the FWs were given.

5.3.1 Who are the fieldworkers in the two community based studies?

Thirty-six FWs and six SFWs were employed in the two case studies. Table 5.3 provides demographic details of 36 FWs, majority of whom were males; 7/10 and 25/26 in CSA and CSB respectively.

Table 5.3: Demographic characteristics of FWs in the case studies

Socio-demographic characteristic	Case study A FWs Number	Case study B FWs Number
Total number	10	26
Gender (female)	3/10	1/26
Mean age, years (range)	26.5 (20-34)	27.81 (21 – 38)
<24 yrs	4	7
25-29	3	10
30-34	3	6
35-39	9	12
Marital status (married)	2	9
Education, average (range) years of schooling	12.2 (12-14)	12.31 (12-14)
12 years - O-level-	9	22
14 years - College/diploma	1	4
Average period (months) worked at KEMRI-WT	7.3 (5-9)	10.13 (0.1-16)
<=5 months	4	5
6-10 months,	6	9
11-15 months,	None	4
16-20 months,	None	8
Number of FWs with relatives participating in the study	1	11*
Contract period offered	9 months**	2 years

* Of the 26 FWs in case study B, six had 1 relative each participating in the study, four FWs had 2 relatives and one FW had 6 relatives

**Three of the 10 FWs in vase study A had their contracts extended for between 3 months to 1 year. Of the 3 FWs, two had contracts in the same study cleaning data collected in the case study while the best 'performing' field worker was given a one-year contract with another study.

The respective average ages were 26.5 and 27.8 years, with the majority aged 25-34 years, and not married. Many of the FWs had worked for KEMRI-WT for less than 10 months. Only one FW in case study A had relatives participating in the case study, while 11/26 of FWs in case study B had at least one relative participating in the study.

All six SFWs in the two case studies (one in CSA and five in CSB) were male, and had 12 years of schooling (Table 5.4). The average age for SFWs in case study B was 29.2 years (range of 25-35years), with half aged below 29 years. Only one SFW in case study B had three relatives participating in the study. The rest had no participating relatives partly because they were not residents of the study locations. The SFW in case study A had 12 years of working for KEMRI-WT, of which 11 were as a FW. The mean period of working for KEMRI-WT for the five SFW in case study B was 4.8 years (range 3-8 years), with half employed for less than five years.

Table 5.4: Demographic characteristic of SFWs in the case studies

Demographic characteristic	CSA SFW	CSB SFWs
Number of SFWs	1	5
Age in years (mean, range)	36 years	29.2 (25-35)
24-29yrs, (number, %)	N/A	3 (60)
30-34yrs	N/A	2 (20)
35-39yrs	1	2 (20)
Employment duration (mean, range)	12 years	4.8 (3-8)
1-5yrs, (number, %)	N/A	3 (60)
6-10yrs	N/A	2 (40)
11-15yrs	1	N/A

In both case studies, the FWs (or Junior FWs) were employed at the beginning of the studies and resided within the study area. Case study A also employed Community

Based Assistants (CBAs)[45] to help FWs with their work. Both the FWs and CBAs ended up doing similar work, despite having been employed on different pay scales and grades.

In both case studies, employing community members as FWs was in line with institutional policies on FW employment, described earlier in 5.2.1. FWs were offered contract periods based on study duration. FWs in case study A had a 9-month contract, while those in case study B had a 1-2 year contract, extendable to the 3 years of the study duration. FWs were aware that the short study duration could not allow for promotion, but that the PIs and supervisors had considerable influence over contract renewals and extensions; influences which formed an important backdrop to how FWs performed their roles.

In line with institutional policies on staff employment, FWs in both case studies were recruited through advertisements widely distributed within the study population. In case study B, a recommendation letter from the village elder attesting to local residency of the applicant was required. Shortlisted candidates were interviewed by a panel of KEMRI-WT staff, and successful ones introduced to community members in community meetings.

5.3.2 Hopes, expectations and anxieties about being employed at KEMRI-WT

In all interviews, almost all FWs described being excited about taking up their job with KEMRI-WT, as such a job (they believed) offered them much needed income, opportunities for further education, respect in the community, and an ability to help

[45] CBA are of slightly lower qualification grade than FWs. This cadre has been removed from the newly restructured FW career pathway (2012) and the staff were redeployed as FWs.

their community access much needed health care and aid. Some of these hopes were based on expectations of personal gains, or perceptions of KEMRI-WT as a good quality hospital, rather than a research institute, as is common in the community.

> "I felt happy, I had wished to join KEMR since long time ago ... [because] most of the KEMRI staff drive (own cars), and the further education that I hear people get when they join KEMRI..." (FW6, female, CSA/FGD06)

> "I feel good being associated with KEMRI because I think now the community is looking at me from a better perspective as compared to before I joined (KEMRI), because I have been able to interact with the community, and in fact some of the families that I had no close relationship with, I feel like I am a member of those families...." (FW5, male, CSA/FGD05).

Initial excitement was counterbalanced by apprehension towards the job itself and of what KEMRI-WT is about because of associated rumours, as described in 5.2.3. All the 36 FWs reported having heard of rumours of KEMRI-WT and devil worship.

> "... I was going for the interview and on the way, I was just told 'you are going to KEMRI? I am telling you your days are numbered' (*all laugh*) 'you have forgotten about [a FW from the area] who died recently?...'" (FW9, male CSB/FGD09).

Some FWs expressed an initial strong belief in the rumours, but took up the job anyway reasoning that it would take a long time before it harmed them as evidenced by only a few deaths of KEMRI-WT staff over the years. Others sought information from 'trusted sources' including current KEMRI-WT staff. The majority of the FWs, however, reported that initial induction training was very important in addressing their concerns and making them aware of community perceptions of the research centre, and how those perceptions were likely to affect their work.

"...okay with me sincerely speaking I used to believe that it (KEMRI) is [a devil worship organization] because of the kind of vehicles and the kind of salary. But after the seminar [training on KEMRI and research ethics] and after the experience of the kind of job, I came to realize that the salary that we are being paid it's not big at all compared to the kind of work we are doing..." (FW1, female, CSA/FGD07).

Initial anxieties towards KEMRI-WT were quickly replaced by apprehension about the type and the sheer amount of work FWs were expected to perform. Additional anxieties for some FWs were the fear of being rejected in those villages they were not residents of, but which they were supposed to cover. FWs were not employed in the villages with only a few participants to reduce research costs. Ramifications for FWs working in those villages were that they were having to justify how they got employed (and that they did not bribe anyone), and being blamed for taking up jobs meant for members of that village. Other FWs felt that such difficulties stemmed from jealousies of those who missed out on KEMRI-WT jobs.

"On the issue of fieldworkers working in neighbouring villages...my people they feel happy (since) there is a person from their own village (working at KEMRI). However, in some other places like [village name] the people are not happy, they say 'mmh, why is it that somebody from very far away is the one who is working in our area? Why not people from our area?'" (FW2, male, CSB/FGD09).

5.3.3 Fieldworker roles in the case studies

I grouped the formal (given) roles of FWs in the two case studies according to the stages of research outlined in Figure 2.2.They include roles in 'formal[46]' community

[46] Refers to community engagement processes that were planned for and implemented by the study teams.

engagement processes, in participant recruitment and in consenting processes, in data collection and at study exit. I discuss these in turn.

Formal Community engagement activities

In both case studies, FWs were minimally involved in 'formal' community engagement processes. They were consulted for advice on sensitive information and procedures, and on ways to address rumours and concerns about the study and KEMRI-WT generally. FWs helped mobilize community members for public community meetings, where they were also formally introduced to the community and had their roles explained.

FWs were involved in 'informal' community engagement throughout their stay in the community (both during and after end of studies) through discussions with their peers, family members, and others in the community about the study, KEMRI-WT and their roles. FWs anecdotally described discussing with researchers issues they became aware of through informal interactions with participants and community members, and which had potential to substantially affect study recruitment and retention; such as rumours on safety of study procedures discussed in 8.5.

Participant recruitment and study consent

FW roles in both case studies were most pronounced at recruitment and follow-up stages of the research. Consenting processes in the two case studies differed due to the nature and type of participants (entire households in CSA and young children in CSB), and different levels of familiarity by the population with KEMRI-WT activities (more within the KHDSS[47] in CSA and less outside the KHDSS in CSB). Case study A

[47] KHDSS – Kilifi Health Demographic Surveillance System, see 3.6.

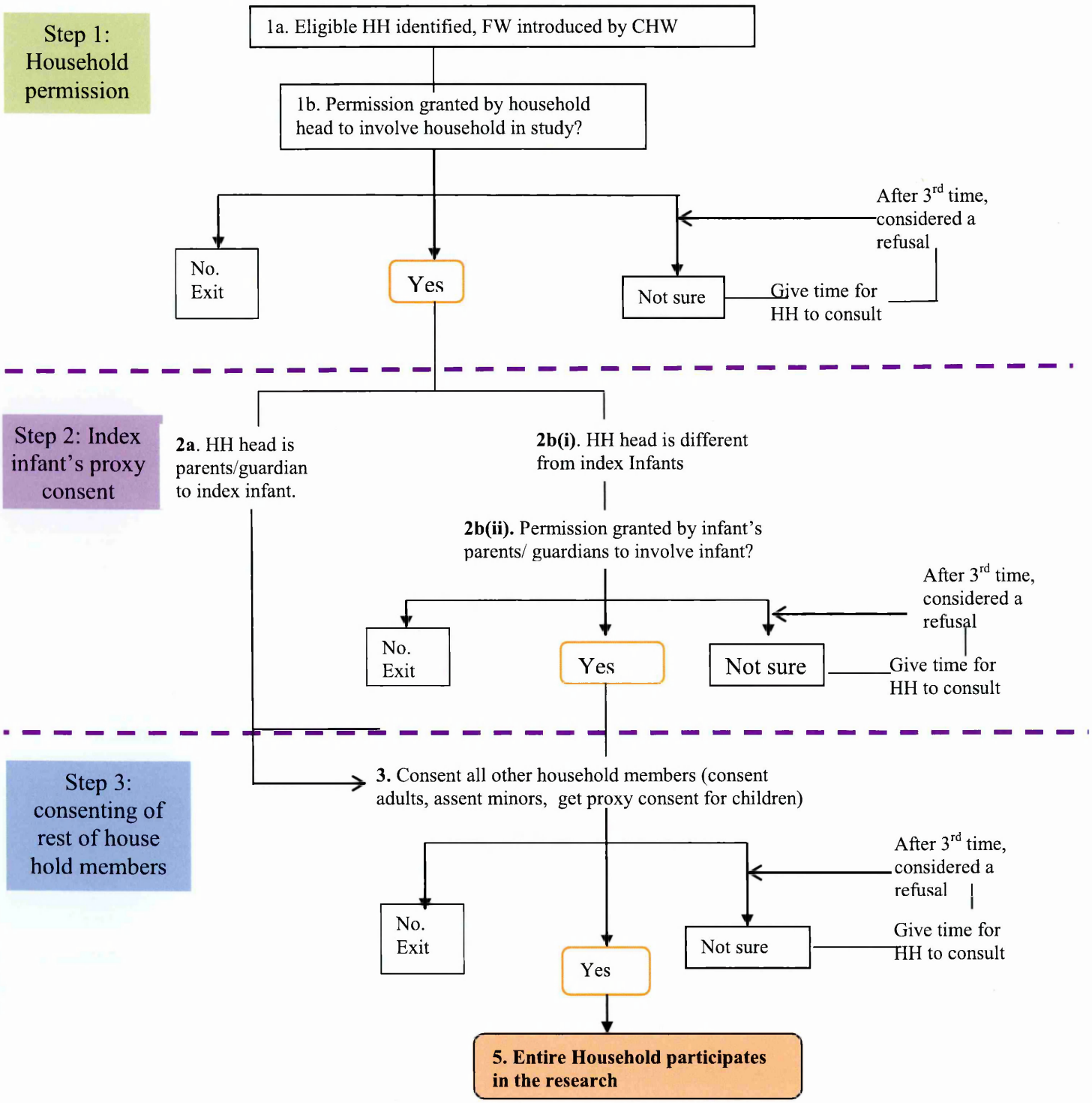
required consent from all household members while case study B required proxy consent from parents or guardians of the child.

i) FWs roles in recruitment and consenting for case study A

For Case study A, on patterns of transmission of a respiratory virus, RSV, within families, the infant was the central focus of the study. The initial design of the consenting process assumed the decision of the household head and the infant's parents were the most important, with remaining household members likely to support their decision. In practice, FWs found research decision-making processes at households complex, with multiple levels of decisions and diverse interests of household members (as described 7.2.2). Over time and with advice of the researchers and the CAST[48], a multi-stage consenting process was adopted, which I simplified into three main stages as shown in Figure 5.5. The first stage involved seeking permission from the household head to involve the entire household in the research. The second stage included seeking consent from parents/guardians of the index infant if these were different from the household head, which was often the case. The final stage included seeking consent from all household members. This included consent from all adults, and assent from minors of 13-17 years. There were many challenges with the process, as discussed in 7.2.2. At each stage, where the household members were undecided, or requested for more time, FWs were supposed to follow-up to a maximum of three times. Thereafter, the household was considered a refusal.

[48] As described in 3.6.1, CAST is team consisting of the study PI (chair), immediate FW supervisors and members of the community liaison teams (including a social science researcher) set up for a specific study to advise on community engagement activities and issues that emerge during the implementation of the research.

Figure 5.6: Consenting process for case study A



ii) FW roles in recruitment and consent for case study B

For case study B, a malaria vaccine trial, different approaches to consenting were followed across the 2 age-groups (6-12 weeks and 5-17 months). For the 5-17 months age group, potential participants identified by Community Health Workers[49] and local administrative leaders were invited to a central meeting within their village where information about KEMRI-WT and the study was given by the study PI and the community facilitators. The informed consent form (ICF) was used to explain the study and discuss issues such as amount and frequency of blood samples and safety of trial vaccines. Interested participants were registered and invited for screening at the nearest health facility, and linked up with the area FW for subsequent follow-up visits. FWs' roles at this stage included following up potential participants in their homes, clarifying areas of concern, and organizing for transport and meals for participants with scheduled health facility visits.

For the 6-12 weeks age group, FWs identified and provided initial study information to parents/guardians of the children. FW identified potential participants through various channels; liaising with CHWs, village elders, dispensary staff, and working with community social network groups such as women groups, and recruited participants. Parents/guardians willing to consent their children were invited to the nearest health facility where the study clinician revisited the study information; and where those willing to consent their children signed the ICF in the presence of the study clinician.

[49] Use of CHWs and local leaders to recruit participants was because the study was happening in a locality about 30 kms from the area covered by KDHSS. As part of collaborating with MOH, the study was advised to work with CHWs. However, later on these process was abandoned and FWs who by then were employed were involved in subsequent recruitment activities (Vibian, 2012).

FW roles at study follow-up/data collection phase

The bulk of FW roles in case study A was at follow-up activities, which involved at least twice weekly visits to each participating household for the six-months period of the study. FWs collected various data at each follow-up visit including illness history, temperature measurement and nasopharyngeal flocked swab (NFS) from each household member twice a week, respiratory rate for all children under 5 years at each follow-up visit, and an oral flock swab (OF) timed at one minute per person on alternative visits (that is, once a week). Photo 5.1 shows CSA FWs visiting one of the participating households. The numerous challenges FWs faced in collecting the data, especially the NFS, are discussed Chapter 7.

Photo 5.1: FWs in case study A following-up one of the participating households

The follow-up period for each participant in CSB was up to 3 years, with follow-up frequency staggered as per study procedures described in 4.3.2. FWs followed up participants for 6 consecutive days immediately post-vaccination, and thereafter at least

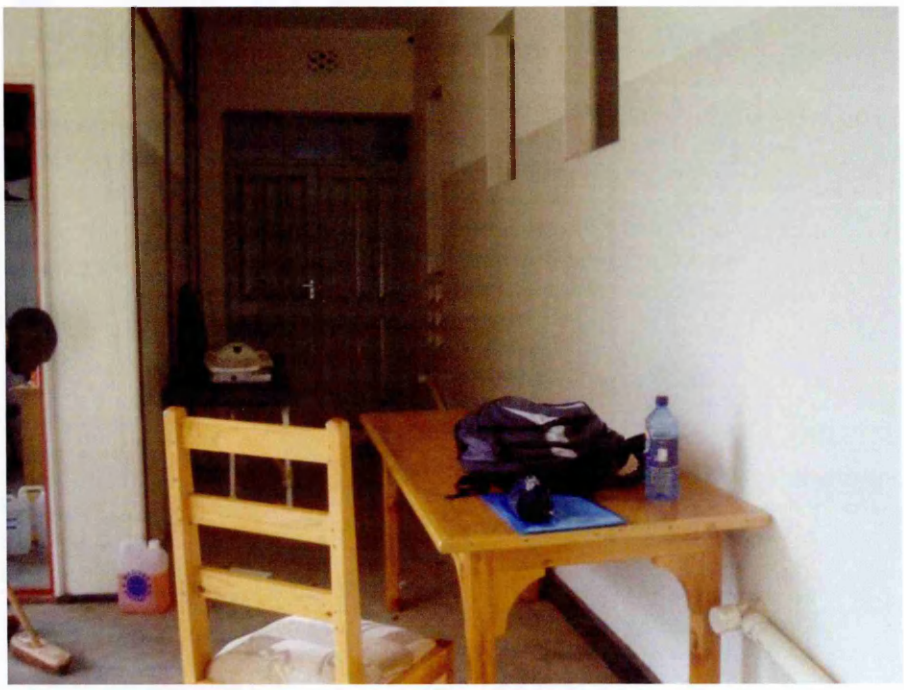
once a month for the reminder of the study period. Activities at follow-up included checking the general health of the child, reminding participants of scheduled visits and recording passive case detection (PCD)[50]. Children who fell ill at night were immediately followed-up by the nearest FW and, in consultation with the study clinician, given an analgesic (paracetamol) as first aid. Where such children were seriously ill based on FW assessment and on-phone communication with the study clinician, FWs organized for transport, and accompanied them to the nearest health facility. Photos 5.2 and 5.3 show one of the three sites of CSB, which was integrated within the MOH facility.

FW roles in CSB also included coordinating transport and meals for participants attending a scheduled clinic and/or vaccination visit at the health facility. FWs were also allocated rotational duties at the health facility, which included general cleanliness, keeping records for all participants attended, taking temperature, respiratory and anthropometric measurements for all children under five years, and organizing for transport and meals for all participants visiting the health facility during the day

[50] Following up for PCD refers to FWs following a participant who had been ill and was attended at a health facility in order to record information on diagnosis, treatment and appointments if any.

Photo 5.2: One of the sites of case study B

Photo 5.3: A case study B office site inside a public health facility



FW roles at Study exit:

The short duration of case study A (six months) meant that I could observe and interview FWs (and others) at study exit. This was not possible for case study B as it

was still going-on by the time of writing this thesis. FWs role at exit of case study A included delivering messages about the end of the study, and tokens to participating households.

In summary, the formal roles for FWs were most pronounced at participant recruitment, consenting processes and at study follow-up, and less pronounced in formal community engagement activities and at study exit. The nature and amount of work for FWs in the two case studies differed at follow-up stages, with FWs in CSA more intensely involved at data collection compared to CSB FWs. This also presented unique challenges and opportunities for the FWs, as discussed in subsequent chapters, and for the type of support FWs required, discussed in 8.5

As described in 5.2.3, a key factor influencing the nature of interactions between FWs and the community is community's perceptions of the research centre. The household quantitative survey, described in 4.4, included data on levels of understanding of research as the main role for KEMRI, and the nature of interactions between FWs and the KHDSS community.

5.4 Community views of the research centre and of FWs

364 of the 416 households (85.7%) visited for the household survey were interviewed; 52 had out-migrated. Data were analysed for 362 respondents; data from two respondents were dropped as we judged them as incomplete[51]. Table 5.5 presents the socio-demographic characteristic of the respondents whose data were analysed.

[51] The two respondents appeared reluctant to respond to survey questions, i.e. gave "don't know" responses and did not want to withdraw even when reminded of their rights to do so.

The majority (59%) of respondents were female and were either the household head or spouse(s) of the household head (55%, n=199). The mean age was 43 years, with the largest group (48%) being 31-50 years of age. There were more female than male respondents in younger age groups. The majority of respondents had primary level education (44%); 39% had no formal education while only 15% had secondary level education or above. 68% of the respondents declared a religion.

Table 5.5: Socio-demographic characteristics of survey respondents

Social demographic characteristic	Distribution by gender of respondents, and total Number (%)		
	Female	Male	Total
Number of HHs interviewed	212 (59)	150 (41)	362 (100)
Relationship to household head			
Household head	13 (14)	80 (86)	93 (26)
Spouses to HHH	103 (97)	3 (3)	106 (29)
Parent/parent-in-law	72 (60.5)	47 (39.5)	119 (33)
sibling	1 (20)	4 (80)	5 (1)
Related in other ways	23 (59)	16 (41)	29 (11)
Age group of respondents (years)			
<30 years	54 (65)	29 (35)	83 (23)
31-50	118 (67)	56 (32)	174 (48)
51-70	33 (40)	50 (60)	83 (23)
>71	6 (35)	11 (65)	17 (5)
Missing information	1 (20)	4 (80)	5 (1)
Levels of education			
No formal education:	104 (74)	37 (26)	141 (39)
Adult education	5 (71)	2 (29)	7 (2)
Primary education	80 (51)	76 (49)	156 (43.7)
Secondary education (7-14 years)*	17 (40)	26 (60)	43 (12)
Tertiary education	4 (40)	6 (60)	12 (3)
Religion			
Christians	89 (62)	55 (38)	144 (40)
Muslims	33 (53)	29 (47)	62 (17.1)
Traditionalist	3 (1.4)	5 (3.3)	8 (2.2)
Others (e.g. SDAs, Jehovas Witness, Hindus)	19 (9.9)	14 (9.34)	33 (9.1)
Did not profess any religion	68 (59)	47 (41)	115 (31.8)

* Includes respondents of previous system of education in which secondary included both O- and A-levels (up to 14 years) and the current system with only O-level (up to 12 years).

Understanding the main role of KEMRI-WT as research

All the 362 respondents described having heard of KEMRI-WT. The majority (68%) described KEMRI-WT as a hospital or as giving aid, with no apparent knowledge of KEMRI-WT's research role (see Table 5.6). Nearly a third (31.7%, n=115) of respondents described research as a main role for KEMRI-WT. The majority (78.5%) of 362 respondents supported the work of KEMRI-WT, of whom 59.4% reported being strongly supportive. Only four respondents (1.1%) reported being unsupportive, while 75 (20.4%) reported being indifferent towards the work of KEMRI-WT.

Table 5.6: Community members' description of the role of KEMRI-WT

Indicator	Female Number (%)	Male Number (%)	Total; Number (%)
Total number	212 (58.6)	150 (44.4)	362 (100)
*Understanding of research**			
Described research (clear and partially)	48 (41.7)	67 (58.3)	115 (31.8)
Did not seem to understand research	164 (66.4)	83 (33.6)	247 (68.2)
Supportive of KEMRI-WT's work (likert scale)			
Strongly supportive	122 (57.6)	93 (62.0)	215 (59.4)
supportive	38 (17.9)	31 (20.7)	69 (19.1)
Indifferent	49 (23.1)	25 (16.7)	74 (20.4)
unsupportive	3 (1.4)	1 (0.7)	4 (4.4)

*includes those who clearly described research (n=69) and those who partially described it (n=46)

Table 5.7 shows the characteristic of the respondents who described KEMRI-WT's role as research. The majority of the 115 respondents who described research as the main role for KEMRI were males (58.3%); were aged less than 50 years (73%) and had at least primary level education (59%). 82.6% of those who described the work of KEMR-WT as research, and 76.8% of those who did not, supported the work of

KEMRI-WT. This suggests that there is a strong support for KEMRI-WT's work irrespective of 'understanding' of its main role as research.

Table 5.7: Characteristics of survey respondents who described KEMRI-WT's roles as including research

	Described research Number (%)	Not described research, Number (%)	Total respondents Number (%)
Total respondents	115 (31.77)	247 (68.2)	362 (100)
Education levels			
No formal education	19 (16.5)	122 (49.4)	141 (39.0)
Adult education	2 (1.7)	5 (2.0)	7 (1.9)
Primary education	50 (43.5)	108 (43.7)	158 (43.7)
Secondary education (9-14 years)*	34 (29.6)	10 (4.1)	44 (12.2)
Tertiary education	10 (8.7)	2 (0.8)	12 (3.3)
Relationship to HH head			
Household head	36 (31.3)	57 (23.1)	93 (25.7)
Spouse	25 (21.7)	81 (32.8)	106 (19.3)
Parent/parent-in-law	40 (34.8)	79 (32)	119 (32.9)
Sibling	1 (0.9)	4 (1.6)	5 (1.4)
Other	13 (11.3	26 (10.5)	39 (10.8)
Age of the respondents (years)			
<30	21 (18.3)	62 (25.1)	83 (22.9)
31-50	63 (54.8)	111 (44.9)	174 (28.1)
51-70	27 (23.5)	56 (22.7)	83 (22.9)
>71	2 (1.7)	15 (6.1)	17 (4.7)
Don't know	2 (1.7)	3 (1.2)	5 (1.4)
Supportive of KEMRI-WT's work (likert scale)			
Strongly supportive	71 (61.7)	144 (58.3)	215 (59.4)
Supportive	24 (20.9)	45 (18.2)	69 (19.1)
Indifferent	19 (16.5)	55 (22.3)	74 (20.4)
Unsupportive	1 (0.9)	3 (1.2)	4 (1.1)

Visits by FWs in the last 6 months

Table 5.8 shows the frequency of and reasons for FW visits. The majority (78%) of the 224[52] respondents reported having been visited at least once by a FW. 73% (n=165) of the respondents described the reason for the FW visit as collecting information about

[52] Data was analysed for the 224 who reported being visited by a FW; of the remaining 138 respondents whose data was not included; 72 reported not having been visited while 66 did not know as they might have been away.

the family, 7.7% (19) as being treatment or other study-related activities, 3.9% (10) as consent for research, and 4 % (13) as collection of samples such as blood or nasal swabs. Two people (0.8%) did not know the reasons for the FW visit while a further 8.9% (22) did not provide answers.

Table 5.8: Frequency and reasons for FW having visited survey respondents in the community

FW visit to HH	category	number (%)
Number of times visited by a FW* (n=226)	Visited once	165 (73.0)
	Visited twice	42 (18.6)
	Visited three or more times**	16 (7.83)
Reasons given for FW follow-up visit (n=248)	Collect information about family/census	182 (73.4)
	Followed-up for treatment/study follow-up	19 (7.7)
	Consent (being asked to join a study)	10 (4.0)
	Collecting samples (blood, nasal etc)	13 (3.95)
	Not know	2 (0.8)
	Others	22 (8.9)

* Three respondents (1.3%) who did not know the number of times their homes were visited by a FW were dropped in this analysis.
** Includes three respondents in case study A, who reported being visited up to 24 times in 4 months.

FW visit and understanding of research

Table 5.9 shows the trend between number of FW visits and 'understanding of research' as the main role for KEMRI-WT. Similar proportions of those who described research (63.4%) and those who did not (60.7%) were visited at least once by a FW. The test for homogeneity and for odds ratios between those who described research (cases) and those who did not (controls) shows statistically significant differences at varying education levels, but not in the other categories of age of respondent and number of FW visits.

The univariate logistic regression for direction and strength of trend in each of the three variables showed a statistically significant positive relationship between describing research and increase in education level (see Table 5.9). There was a 3-fold increase in

'understanding research' at primary education compared to no education (which is the baseline used); the corresponding increases of 'understanding' at secondary and tertiary levels were 21-fold and 30-fold respectively.

Figures 5.7 to 5.9 show this data diagrammatically.

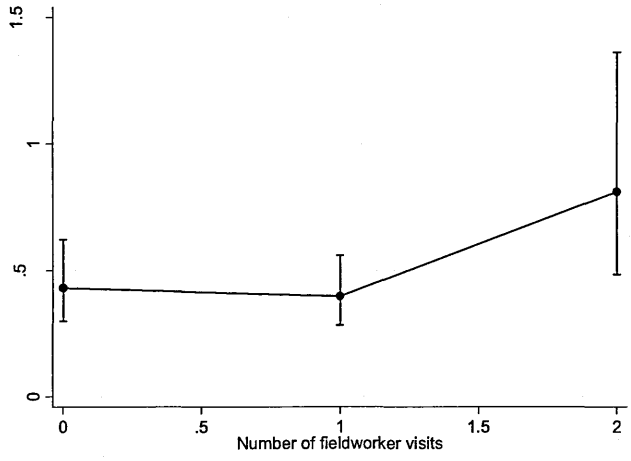
While it seems that there was no significant association between number of FW visits and understanding research, it is difficult to conclude further because other variables such as education levels appeared to affect this (or the lack of) association.

Table 5.9: Trend between FW visit and 'understanding' research as the role of KEMRI-WT

Indicator	Cases (desribed research)	Controls	Odds	Test for homogenity*	Test for trend of odds	UL odds ratio** (n=115)
Frequency of FW visit						
None	42	97	0.432	$Chi^2 = 5.53$	2.48	
Once	47	118	0.398	P = 0.0628	P=0.1153	0.92
Twice or more	26	32	0.813			1.88^{β}
Agegroups						
=< 30 years	21	62	0.34	$Chi^2 = 3.54$	$Chi^2 = 0.17$	
31-40	32	57	0.56	P = 0.31	P = 0.682	1.68
41-50	31	54	0.57			1.42
>=50	29	71	0.41			0.39
Education levels						
No education[p]	21	127	0.165	$Chi^2 = 77.0$	Trend = 70.6	
Primary level	50	108	0.463	P<0.001	P<0.001	$2.80^{®}$
Secondary level	34	10	3.400			$20.56^{®}$
Tertiary	10	2	5.00			$30.23^{®}$

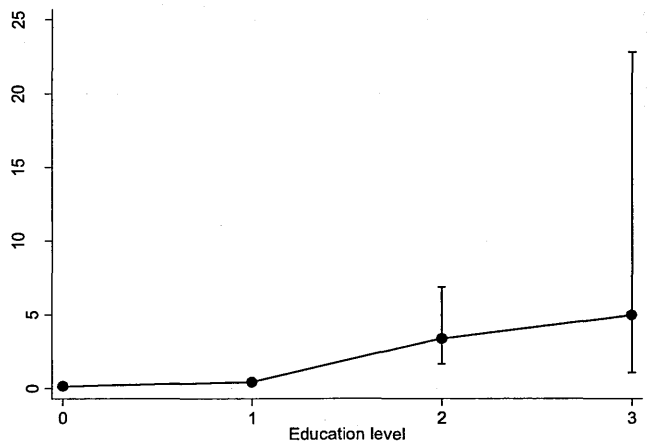
*test for the probablity that the odd ratio are the same
** Univariate logistic regression
$^{\beta}$ p = 0.050 at border line
$^{®}$ P < 0.001

Figure 5.7: Odds ratio for 'understanding' research against number of FW visits



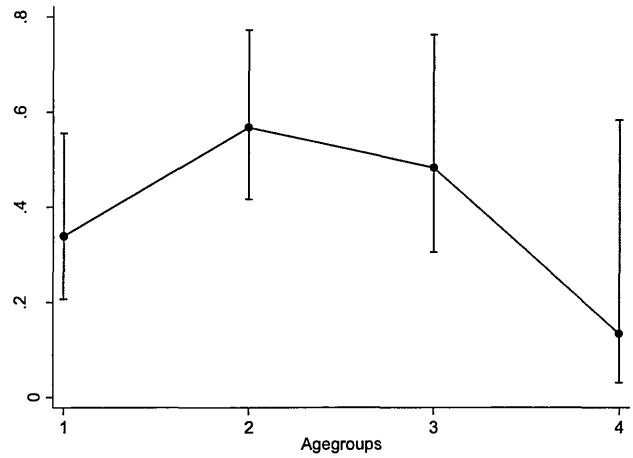
Legend: Number of FW visits:
0 = not visited
1 = visited once
2 – visited twice or more times

Figure 5.8: Odds ratio plot for 'understanding' research against education level



Legend: Education level:
0 = Not gone to schools
1 = Primary education
2 = Secondary education
3 = Tertiary education

Figure 5.9: Odds ratio for 'understanding' research against age-group



Legend: Age groups:
1= less or equal 30 years
2 = 31 – 50 years
3 = 51 – 70 years
4 = More than 70 years

Views on nature of interactions: focus in trust

The second area of interest in the quantitative survey was community feelings towards the FWs in terms of trust. The qualitative interviews with CLG members on community perceptions of the research centre (5.2.3) suggested ambivalence; with high regard and support for quality health care provided by KEMRI-WT and mixed feelings towards research activities. I used likert scale questions, to get an overview of community members' views with regards to trust towards FWs.

The likert scale analysis, presented in Table 5.10, shows that: the majority (83%) of respondents agreed that FWs always try to explain their work clearly; 77% agreed that the FWs are always truthful; and 86% agreed that overall, FWs are good at what they do. 18% of respondents felt that their households are visited too often.

Table 5.10: Community feelings towards KEMRI-WT's FWs

Total respondent (362)	Agree (%)	Neutral (%)	Disagree (%)
KEMRI-WT FWs who visit homes always try to explain their work to HH clearly	302 (83%)	39 (11%)	20 (6%)
Household is visited too often by KEMRI-WT FWs	65 (18%)	45 (12%)	252 (70%)
KEMRI-WT FWs are always truthful in the way they give information and answer questions	278 (77%)	68 (19%)	14 (4%)
Overall KEMRI-WT FWs who visit homes are good at what they do	310 (86%)	45 (12%)	6 (2%)

To test for overall feelings towards FWs, I developed a weight score, assuming agree and disagree on a continuum scale of 0 (disagree), 1 (neutral) and 2 (agree). The maximum expected score for a respondent who viewed FWs positively in all four questions would be 8, and the minimum would be zero. Table 5.11 shows the collective scores against frequency of FW visits. The majority (85%) of the respondents scored 6

and above, with nearly half (49%) having the highest score of 8; showing combined positive views towards FWs.

Table 5.11: Overall feelings towards FWs

Overall score*	Number of FW visits (frequency)			Total Number (%)
	None	Once	Twice or more	
2	2	2	1	5 (1.4)
3	2	5	0	7 (1.9)
4	8	6	0	14 (3.9)
5	11	7	6	24 (6.6)
6	34	31	14	80 (22.1)
7	23	18	7	48 (13.3)
8	53	96	29	180 (49.4)
Total (freq. 5)	136 (37.5)	165 (46.5)	58 (16)	358 (100)

*Data missing for 4 respondents.

The quantitative data shows generally positive views about KEMRI-WT and FWs from the KHDSS respondents. This differs from the generally negative impression from the interviews with CLG members, in which it seems that KEMRI-WT and the FWs may not be well received in the community. There are several reasons for these differences.

Firstly, it is possible that, in group discussions, rumours are exciting narratives that get discussed for a long time. Secondly, being part of KEMRI-WT organization, staff were more likely to point out issues that are likely to impact negatively on the image of KEMRI-WT. Thirdly, and possibly most importantly, one of the focal areas for this study was the challenges that KEMRI-WT FWs face in interactions with participants. This was likely to elicit issues and negative aspects rather than provide a balanced view. I reviewed subsequent interview guides to elicit a more balanced view.

Finally, it is possible that response bias (respondents giving answers that appeal to the enumerator) could have been introduced in the household survey as the enumerators were KEMRI-WT employees. As discussed in 4.7.4, it is difficult to interpret likert scale answers beyond the general overview they provide. Combining qualitative and quantitative methods, in this case, provided both depth (from qualitative methods) and an indication of the spread of issues (from quantitative methods).

5.5 Chapter conclusion

Fieldworkers at KEMRI-WT are local community members with at least 12 years of schooling employed into research activities. The FW group includes staff of different designations, with the main ones being Junior FWs and Senior FWs. There are generally more male than female FWs at the research centre. FWs carry-out a range of research activities including recruitment of participants, undertaking consent processes, and performing simple non-invasive procedures.

Employment of FWs is highly appreciated in the community for providing an income to young people. In addition to facilitating cultural responsiveness of research, FWs form a cohort of community members with exposure to and experience of research activities, with potential to create mutual understanding between the community and the research centre through their interface roles. However, within a socio-political context of limited employment opportunities, there are several competing interests for FWs; those who miss out on KEMRI-WT employment may be very disappointed.

An expectation for FWs joining the research centre is to earn a good salary and secure long-term employment at the research centre. Even when informed of the contractual

nature of their employment, many FWs reported being hopeful of contract extension, since there are many long-term FWs whose contracts get renewed. Data on FW progression showed an unclear career pathway with few opportunities for career advancement beyond senior FW level. In addition, many FWs reported being unhappy with involvement of immediate supervisors and PIs in decisions about their promotion. These issues matter to staff in a context of limited job opportunities for the majority of the population, as is the case in our context.

Study designs for the two studies were such that participants would be followed at home and sometimes during out-of-office hours. This required that the studies employ people who are known by and reside within the community where the research is being conducted, and are conversant with local norms of the study population. FW roles involved significant following-up of research participants at their homes, and therefore social interactions with the participants were a key feature of the FW roles.

Given the importance of community members' understanding of research and of their views towards FWs on FWs roles, I presented quantitative data from the household survey. The quantitative survey showed strong support of the research centre and of the work of FWs in the community, but that this support was often based on an understanding of KEMRI as a health care provider, and possibly of FWs as 'doctors'. For example, only 32% of the 362 respondents appeared to have some understanding of research as the main role of KEMRI; the majority (68%) described KEMRI as a health provider or an aid organization. It also emerged that community views of the research centre were extended to its staff, and vice versa. For FWs, these views may facilitate their being accepted and trusted by the community, or rejected and doubted. Although the quantitative data suggests an overall positive perception, qualitative data shows

significant challenges and complexities for fieldworkers, discussed further in later chapters.

The findings presented in the next three empirical chapters are based on the qualitative research conducted in the two community based case studies. In the next chapter, I start to discuss the nature of FW-participant interactions by first describing the issues that participants brought to the research negotiation space; their expectations, hopes, worries and concerns, and how these influenced the decision they took with regards to research participation.

CHAPTER 6 Participants' hopes and fears about the studies, and household decision-making patterns

6.1 Introduction

In Chapter 5, I presented an overview of FWs in KEMRI-WT research centre and the institutional context in which FWs perform their roles, including the extent to which they feel they are valued. In this chapter, I address objective 2 of the thesis: *to describe two key areas framing the interactions between FWs and participants in the case studies: household decision-making norms around research participation; and participants' hopes and anxieties.* I have divided this chapter into two main sections:

- participants' hopes, fears and anxieties as discussed by FWs, researchers and participants in the two case studies (6.2); and
- household decision making dynamics, and how these shaped the nature of interactions between FWs and research participants (6.3).

As described in chapters 3 and 5, the main formal roles for FWs were undertaking consent processes and collecting research data. These roles appeared to be influenced by several factors including community perceptions of the study, and of KEMRI. In this chapter, I describe factors influencing participants' research decisions, because these were sources of worries for FWs and study teams, and underpinned research negotiations. Inevitably, some of the challenges FWs faced, which are the focus in the next chapter, are mentioned here; illustrating the complexity of FWs roles in the field, and of separating interaction issues into neat separate entities.

6.2 Participants' anxieties, fears and hopes

Over the course of my fieldwork, I observed numerous negotiations between FWs and participants, which sometimes took a significant amount of time. Some participants appeared to worry about the studies and procedures, and about how research would affect their social lives. In interviews with case study participants, researchers and FWs, it became apparent that some of the challenges FWs faced were around participants' hopes, fears and concerns, and how these played out in research decisions. Table 6.1 summarises participants' hopes and anxieties as described by FWs and researchers, and participants themselves.

Table 6.1: Summary of participants' hopes, fears, and anxieties, by case study

Participants' views	Case study A	Case study B
Participant's hopes		
High quality health care	• Free care for participants and other family members during trial; and provision of community level benefits	• As with case study A
Research optimism. i.e. optimistic that the research will be successful, including altruism	• Positive research results will lead to a vaccine available within a few years of completion of the study • Recognition of contributing to benefits for future generations	• Vaccine perceived as already working. • Pleased to be pioneer beneficiary of a 'successful vaccine'. • Some recognition of benefiting future generations
Fears and anxieties		
Study procedures	• ***NFS safety.*** Linked to concerns about infections being shared, and frequency and depth of NFS leading to brain damage and future child health problems.	• Worries of severe adverse events such as death; and related to blood samples e.g. are volumes safe? What are blood samples used for? • Infantometer used to weigh infants: perceived as measuring a coffin.
Association with KEMRI activities	• Worries that KEMRI-WT involved in devil worship, linked to wealth, free study benefits	• Same as CSA, worries also associated with blood samples
Particular sensitivities or confusions in ICF information	• Wording on confidentiality worrying • Explanations of what RSV is and where it is in the body unclear	• Anxieties around ICF information e.g. with regards to terms such as randomization, trial, placebo, compensation, and confidentiality worrying.
FW competence	• FWs' ability to perform NFS safely	

6.2.1 Participants' hopes and expectations

Access to health care

In both case studies, the most common and immediate reason given for joining the research was access to high quality health care for participants. This is unsurprising since both case studies provided health care as part of the direct study benefits and KEMRI-WT is often thought of as a hospital (see 3.6). Some case study B participants thought that the experimental vaccine was already working, and the children, including those in comparator groups, were thereby benefitting by through vaccination. Positive results of the research were anticipated to benefit both current and future generations, as explained by one FW:

> "All children will benefit [if the study succeeds] but those who benefit first are the ones who are in the study, because it's only when the research is proved to work, that's when the others who are not in the study will benefit" (Pax6, Female, CSB_FGD14).

Expectations of positive research results, and research optimism

Hopes of positive results and research success appeared to feed into altruistic reasons for consenting. Case study B participants' perceptions of fewer incidents of ill health among participants seemed to strengthen their belief of immediate therapeutic benefits. There were sometimes particularly high expectations of case study B.

> "... malaria has disturbed so many people in this world, children have been dying at a young age, mothers miscarry or children die during delivery because of malaria. So after realizing that there was research being done for preventing malaria so that it does not affect us again, I was really pleased by that issue; and I said it was better to join so that we make a contribution for the vaccine to be found..." (P1, male CSB_FGD13).

> "... I personally liked the study and said leave alone the children, I myself would like to enrol ...because in case I get meningitis and I have been given the

vaccine, it will also help me too. But they said it was for children only. By then I didn't have a child. When my wife delivered our first child I was really happy. I took the child to them but they said the child was too young; that I should wait ... and when he attains the required age to bring to them, he will already be ahead (enrolled). When the child was five months, he joined the study and I was personally happy about it, and I was still trying to see if there was a small chance for me (to join)" (Pax6, male CSB_FGD13).

Dramatically positive views of FWs about case studies appeared to strengthen expectations of positive results in case study B. FWs' generally described the trial as about how well it works, not whether it works.

> "Aah what makes me happy is the way this vaccine is working, it's very good...to me I see that it will be very important that this study vaccine gets to the community, because if children are now not falling sick, that is good reputation to KEMRI.... So what am most happy about is that *the vaccine is already working"* [italics my emphasis] (FW, male, CSB_IDI07).

> "...we tell them this is a trial, we don't stop at that, we continue saying that it has already been done and it's still going on somewhere else and it works *(laughs)*...it's a trial, but it works" (FW3 male CSB_FGD09).

FWs positive descriptions stemmed from periodic reminders from PIs on a previous efficacy trial of the vaccine[53] (see Olotu, Lusingu et al. 2011) and information on preliminary analysis of the current trial, in line with study requirements. FWs were expected to not share this information with participants to avoid protocol deviation. It is also possible that some FWs 'misinterpreted' PI's updates in order to convince participants to stay in the trial, or because they believed the study would have a positive outcome. Some FWs also felt that it was their responsibility to encourage participants

[53] A site for the previous RTSS trial was 30 Kms from the current study site, (see (Olotu, A., J. Lusingu, et al. (2011). "Efficacy of RTS,S/AS01E malaria vaccine and exploratory analysis on anti-circumsporozoite antibody titres and protection in children aged 5-17 months in Kenya and Tanzania: a randomised controlled trial." Lancet Infect Dis **11**(2): 102-109.

to join in something that would benefit them. Fuelling participants' hopes in the study appeared to allay their fears and concerns (discussed next), but also raised expectations of success, potentially leading to problems later if these were not met. As one FW said:

> "... the parents of the participant won't be happy with us (if the trial fails) because we have been telling them that there is a possibility that the vaccine works in that it reduces malaria... they will be expecting (an) increase [in efficacy] but not that it goes down. So, these mothers will be saying that 'you, KEMRI people, are liars. You say you are doing research yet [all along] your assessments were wrong'...if maybe we come with another study, it will be difficult to get participants... (but) we have worked in several places and the (vaccine) results are showing that the vaccine worked, and it has the ability to protect, I don't think it will fail (*laughter*)" (FW9, female CSB_FGD08).

Optimism about the trial outcome, which I call research optimism, seems to have drawn on a perception among some participants that research '*always*' leads to immediate positive results. This fails to recognize the clinical equipoise[54] in trials. The language used to explain research may have contributed to this view, especially where FWs continued to emphasize research benefits. Research optimism may also have been a subconscious strategy by participants to cope with their own and others' concerns about research and KEMRI-WT (discussed below).

Expectation of rewards for participation

Both FWs and participants in case study A, which had no immediate therapeutic benefits, hoped that participation would be rewarded over the course and at end of the study. These expectations were based on the relative wealth of KEMRI-WT, the

[54] The basis for clinical trials is uncertainty about which of the arms, the experimental and the comparator (including the standard treatment), has better outcome or is beneficial to the participant (Fries, J. F. and E. Krishnan (2004). "Equipoise, design bias, and randomized controlled trials: the elusive ethics of new drug development." Arthritis Res Ther **6**(3): R250-255.).

inconveniences for participants, and appeared to be fuelled by FWs primarily in an effort to retain participants, as discussed in 7.2.3.

6.2.2 Participants' fears and anxieties

Fears and anxieties about research participation were primarily related to: being involved in unfamiliar study procedures; safety concerns related to an experimental vaccine (case study B); and anxieties about KEMRI-WT and FW competence. I discuss these in turn.

Fears associated with unfamiliar study procedures:

Participants, FWs and researchers described unfamiliar study procedures as the most common source of anxieties among research participants. The Nasopharyngeal Flocked Swab (NFS) used to take nasal swabs in case study A (Photo 6.1) and the infantometer used to measure an infant's length in case study B (Photo 6.2) were regularly discussed; they were perceived to be riskier than had been explained during consenting processes. Discomfort experienced and reflex tears produced by the NFS seemed to exacerbate these worries.

> "It's because in the nostrils, there's young (soft) flesh, so when he (FW) inserted that thing (flocked swab), if it touches the walls in there (nostril), one feels pain and is irritated, so that's why many people are not comfortable with it (NFS)" (Pax1, male CSA/HH1).

Participants were also wary of the NFS introducing infections, with incidences of headache and flu-like symptoms blamed on the procedure. Some mothers feared infections 'introduced' in children would only become evident later on in life. These concerns led some mothers to request to have the NFS covertly taken from them, rather than their children.

"...she used to say I don't want this child to be taken the swab (NFS), instead swab me and then say that those swabs are from the infant. So I saw that she did not understand why I am doing this work or why the samples are being taken" (FW1, male CSA_FGD05).

The concern with the infantometer used in case study B to measure the height of the infant (Photo 6.2), was that it resembled an infant's coffin. Some parents worried that it confirmed circulating rumours linked to devil worship by KEMRI-WT that there would be 'eventual death' of some children. Use of an infantometer is recommended nationally in public health facilities, but is not in many peripheral health facilities.

"[the method used in] taking the height of the child is a bit confusing to the parents, because the infants are young, so there is no way that they can stand up. So, you will have to lay him/her down and by so doing it [it appears like] someone who is actually dead, so you take the height in that posture" (FW6 male CSB_FGD08).

Photo 6.1: A FW taking a Nasopharyngeal Flocked Swab (NFS) sample

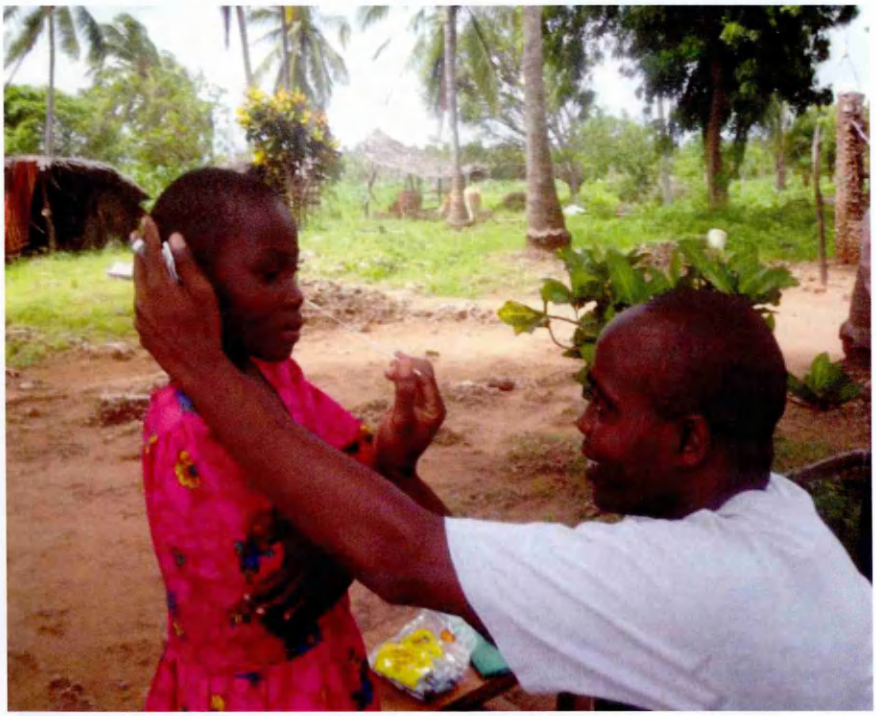
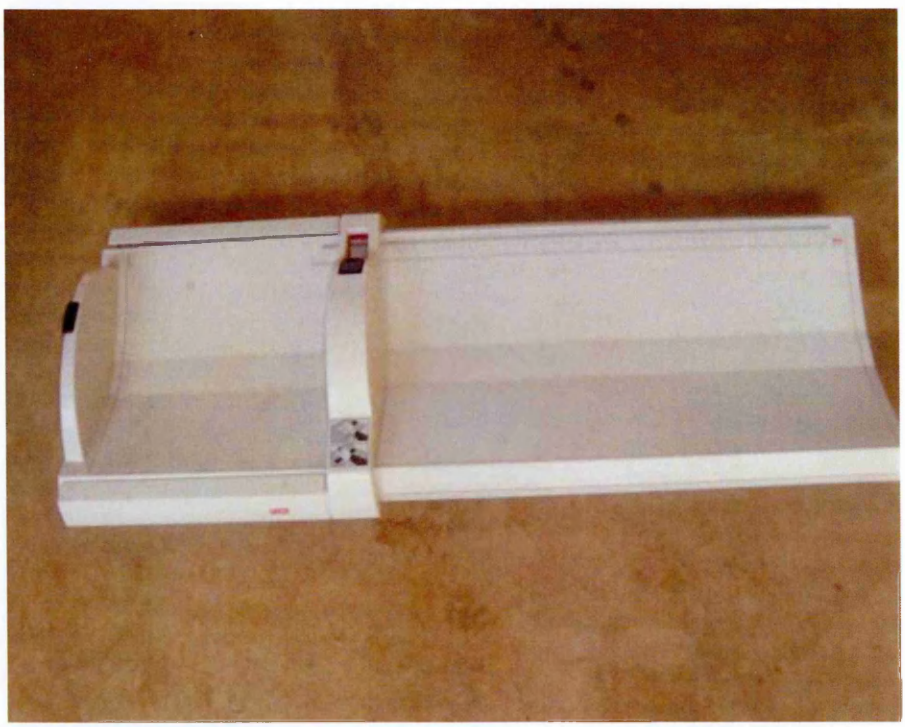


Photo 6.2: An infantometer used to measure infant height



Safety concerns associated with an experimental vaccine

Another concerns with regards to case study B concern was that it was a trial, which directly translates in Kiswahili to '*majaribio*', or 'trial and error'. Some parents worried that the trial had greater risk than those indicated in consent forms, especially when combined with other information such as compensation (see 7.2.1).

> "...and so, at first when we were told, many people were reluctant, to be involved in a trial. They were saying 'aah for my child to be in a trial (*majaribio)*! Do you know what it is and what it will do in a child? ...so how can you agree for your child to be in a vaccine trial?'" (Pax2 female CSB/FGD12)

> "...the thing is this, you know *utafiti* (research) is something for *uchunguzi* (investigation) and *uchunguzi* is trying (experimenting on something); so it's being said the vaccines will be given to the children, what if the children die after they are given these vaccines? What will happen, for example, if my child is given vaccine and dies..." (Pax5, male CSB/FGD13).

Concerns around KEMRI-WT activities

Rumours about KEMRI-WT are widespread among the community (3.6), and appeared to feed into how the studies and procedures were perceived and understood. Worries around blood sample taking in case study B, provision of study benefits in both case studies, and the close monitoring of participants, appeared to heighten concerns in some participants that they would be required to pay back to KEMRI-WT, in unclear ways. Even though the Kilifi site of case study B was overseen and implemented by Kenyans, and the Kenyan PI chairs the multi-site steering committee for the vaccine trial, some community members assumed that a white person (*mzungu*) played the major role, albeit hidden, and wondered about the person's motives.

Some community members also claimed that KEMRI-WT employed FWs from within the study population to facilitate the taking of blood. These allegations appeared similar to a well-known rumour of blood sucking popularly known as *miyani*[55] associated with the introduction of biomedicine and research in the East African coast, in which it was claimed that some local natives were used by their colonial masters to capture and drain blood from their kinsmen, for their masters to sell and become rich.

> "The reason as to why many people feared the KEMRI study is that KEMRI mostly uses blood. In the village or community, the fear is that first, [KEMRI] vehicles have a snake logo, so they are asking why is it that KEMRI's logo is a snake and a snake is an enemy of a human being? ...people say KEMRI people take blood from different people and mix it together so as to sell it, that way they progress (become wealthier) ....can't you see the organization is employing very many people from here? Where does all that money come from? That money is brought by devils" (Pax6 female CSB/FGD14).

There appeared to be a general mistrust towards KEMRI-WT and study researchers, exacerbated by the free "gifts" provided in research; yet such mistrust seemed to counter the commonly given reason for participating in research; to access free 'high quality' health care provided to participants. Paradoxically, there were also concerns that failure to participate in research might lead to denial of much needed health care services, as revisited below.

Concerns about loss of benefits from KEMRI-WT activities

Though not commonly raised, some participants feared that their failure to participate in KEMRI-WT research may lead to it withdrawing from the area, and the community losing out on the health care support that KEMRI-WT provides. A more worrying

[55] See for example White, L. (2000). Speaking with Vampires: Rumour and History in Colonial Africa., University of California Press.p14.

concern because of its implication for consenting processes was a perception that refusing to join KEMRI-WT research may lead to people being denied public health care services, because KEMRI is perceived to be part of, and have great influence over, the public health care system.

> "...other people came and told me to join because I might refuse to join and in future I might experience a certain problem which will force me to go there [health facility]. Then they [KEMRI people] will ask me questions and say, 'we wanted you to join our study the other day but you refused but now that you have a problem, you turn to us and you want us to help?' ... So, I might refuse to join now but in future ... I may find myself going to these people [KEMRI], and so I said its fine I am joining" (Pax1, female, CSA/HH2).

Issues around type, form and distribution of study benefits featured quite prominently in study participation and retention, and are discussed in 9.3.2.

Concerns around FW competence

A concern identified by FWs and researchers (but not participants) at start of the research was with regards to FW competence to carry out 'invasive[56]' procedures such as taking of the NFS. FWs and researchers were especially distressed when they failed to take the sample (NFS) as required in the protocol and had to request for another sample from participants.

> "... yesterday I swabbed a child and then it didn't go normally, she [the child] was disturbing; so I told the mother I needed to take another swab; the mother got really, really mad at me. Then, when somebody else came she would say 'don't accept that doctor because she will do it twice', so it gets difficult; we insist that I have to see it (NFS) go the whole length, and remember this is a child, you cannot be careful enough" (R2, female, CSA/IDI05).

[56] Although the NFS procedures was supposed to be biomedically simple and non-invasive, requiring minimal technical skills, the NFS was perceived by FWs, and some participants as invasive because of insertion of the flocked swab into the nasal cavity.

Participants' anxieties, concerns, and hopes, often played out in household decision-making and negotiations about research participation, discussed next.

6.3 Household decision-making dynamics about research participation

FWs (and researcher) awareness of household decision-making dynamics and how these shifted over time were important for consent processes, and for study retention. Both case studies required either the entire household (case study A) or husbands (case study B) to consent for research.

6.3.1 General descriptions of 'typical' household decision-making norms

Typically, in this patrilineal[57] Mijikenda culture, men are recognised as the heads of households with authority to make most family decisions and to delegate some decision-making areas to others, including their wives.

> "... usually in a family in our culture a woman is married to the man's home, she can't decide anything because she is a visitor ... even if a goat was brought to her from her maternal home ... she can't take that goat and sell it, even if she rears it, without permission from her husband. Because everything which belongs to her is for her husband. So if you say this goat is yours, whom do you yourself belong to? So (in terms of) responsibilities, the man is the head of everything..." (FW1 male CSB/FGD10).

For a married woman, the consequences of disobeying a husband or taking over normative roles of a man can be severe; in extreme cases, she can be beaten, separated/divorced and forced to leave her children with 'their owner'. The divorced

[57] Where descent and inheritance is predominantly through the male household members, Kandiyoti, D. (1988). "Bargaining with Patriarchy." Gender & Society **2**(3): 274-290.;

woman may not be well received in her natal home, given the additional strain on resources and the requirement of the family to return the dowry. As a married woman commented "*You might disagree with him* (husband) *and then where will you go? No you won't go!"* (female-FGD, case study B). Many female participants therefore said they would generally obey their husbands rather than risk the consequences of divorce.

For children perceived to be seriously ill and needing treatment, and where the where the father is away most of the time[58], the parent taking day-to-day care of the child, generally the mother, can often make treatment-seeking decisions. She will often do this in consultation with others in the household. Fears of blame and guilt in the event of a death of the child might contribute to mothers making those decisions.

> "... but let's take for example the husband is away... and my child suddenly falls sick ... in such a scenario will I wait for my husband when the child is sick? No, I will take the child to the hospital. In such a case, the mother makes the decision" (Pax6, female, CSB/FGD12).

6.3.2 Research–related decision making

Is the male household head still a dominant decision maker?

The role of men in study-related decisions appeared to mirror the above normative descriptions. A man making decisions about a child's research participation was described as being appropriate given his position as household head, and given his biological paternity and ownership of the child.

> "... and the mother may say, 'I have agreed, ... but my husband is not present, he must know and decide; I am ready, and even if I don't want (the study) and my husband wants what say do I have?'" (Pax3, male, CSB/FGD13).

[58] This is common in rural Kenya, with married men living in urban centres for work.

It appeared important for fathers to consent for a child's participation because he then took responsibility (including blame) for any research-related risks and adverse events, especially where the study involved blood sample taking and/or unfamiliar procedures.

> "There was one decision I had to make myself and that was during the time of blood taking. She [my wife] was informed at the dispensary but first she came to me and asked about my opinion and I said it was ok if they want to test to know what problem the child has its fine; that's all she asked from me, the rest was up to her to decide," (Pax2 male CSB/FGD15)

Exceptions of male dominance in research decisions

Exceptions of a dominant role for males in parental consent for a child included situations where the husband/father lived away from home for extended periods of time. Here, he often delegated decision-making to others, especially his wife/wives and other household members. FWs interacting with those households were sometimes, but not always, informed of the 'delegated' decision-maker. Mother-in-laws appeared to have significant influence on younger married daughter-in-laws, including in consent decisions for their grandchildren. In other households, especially in case study B where follow-ups at the health facility were needed, the child's mother was given the authority to make consent decisions for the child.

> "...when I told my husband who is the father of the children he said I should decide on my own because if the child will get problems it's me who will get problems because I am the one who stays with the child, not him..." (Pax2, female, CSB/FGD14))

For research involving infants of less than 12 weeks in case study B, participants felt strongly that mothers should be involved in making decisions about their research. Fathers were described as more likely to refuse research (seeing the infant as too fragile), whereas mothers were closer to the child and more aware of his or her

wellbeing. An infant is considered to belong to the mother until he/she can walk because of high level of care he/she requires.

> "It's the mother [who makes the decision] because the child is still very young and so the decision has to be made by the mother; the parent who is always with the child. The mother is the one who can know the stage the child is in and she can decide to enrol the child (in the study)..." (Pax8, male CSB/FGD12).

For unmarried mothers living at their natal home, their own mothers (the children's grandmothers) play a significant decision-making role – including for research - especially where the mother is young, still in school[59] or dependant on her parents (sometimes also 'mature minors'[60]).

Consultation for research-related decisions

Within this pattern of male-dominated decision-making, there were significant amounts of consultation within households about research, for both entire household participation (CSA) and child participation (CSB). Consultation included sharing study information with others for information, to support choices made and/or seek permission to consent. The process of consultation was itself important within households to show respect to others.

> "We (household members) talked amongst ourselves as some were ready while others were not. So we talked to each other until everyone fully agreed. So, we agreed and we cooperated" (Pax1 male, CSA/HH1).

Household consultation appeared to take place for several reasons. Firstly, research participation was described as different from other normal household activities where

[59] In Kenya girls who give birth while still in school, can later rejoin.
[60] Mature minors include women aged below 18 years with children. In consent processes these women are treated as adults.

decision-making responsibilities are known. Secondly, community engagement activities and consenting processes promoted the need for household consultation in advance of consent. Thirdly, the nature of the two case studies (longitudinal with household visits) meant that other household members would find out who was participating; involving all in advance of consent potentially avoided later conflicts.

> "...as the mother you will be informed (about the study) and you will think about it.....and you'll say 'for me to just agree by myself and we are two in the house, if I go alone my husband will come and quarrel with me'. So I will wait for my husband to come and inform him so he understands; and if he tells me to take the child to the study, then I will take the child to the study'" (Pax5 female CSB/FGD14).

Fourthly, consultation within households also allowed consideration of involvement in KEMRI-WT in decision-making, given the rumours and expectations about KEMRI-WT described above.

> "...I worried because people say if you enrol (in KEMRI activities) it's at your own risk. Because you might later on abruptly be asked to give your own person like your relative or yourself, and die... (So) at first I said no, I will think about it, and that's when I had asked for more explanation from him (FW) ...that's why I told him to wait" (Pax1 female CSA/HH2).

Aside from intra-household consultations, participants described consulting other people they trusted, including village elders, CHWs and FWs. A village elder described including his child in CSB as an example to other parents, and to be able to use his experience to 'educate' others seeking information from him.

> "...if you are going to tell your colleague that it is something good, you may be asked how the study has benefited you; that's why we are the ones who started... And it was important for us to first of all enrol our children before others can also enrol theirs ..." (Pax6 male CSB/FGD13).

6.3.3 Discordant decisions about research participation within households

Not all household consultations led to consensus. There was much debate on whose views counted most when parents disagreed (what I term discordant decisions), and initial responses often changed on further prompting. Some women felt strongly they should be consulted and their views taken seriously where research involved children or themselves; and described sometimes resenting male parents' decisions.

> "It's the woman [to make decision], she is the one who carried the child and also struggled to give birth, the man just gave the seeds and then went to drink *mnazi* [local brew] (laughter), therefore it's the woman who has the responsibility to make those decisions" (Pax2 male CSB/FGD13).

Being aware of the consequences of openly defying their husbands' decisions, some women influence and/or subvert male decisions more subtly, to maintain harmony in the home by appearing obedient. Subversive strategies included 'misinforming' the husband of the study (for example exaggerating study benefits), and ensuring buy-in from other more influential household members. Fathers seemed aware that their wives subverted their decisions when in disagreement, but felt unable to prevent such covert strategies. These issues are revisited in 7.3.

> "If the father wants the child to join [the study] but the mother doesn't want that, the child won't go. If you tell your wife to go somewhere where she doesn't want, that will never happen, and there is nothing you can do about it... you can chase her away, but then will you cook for the children?" (Pax1 male CSB/FGD15).

6.4 Chapter conclusion

Across the two case studies, the interplay between hopes, anxieties, and fears appeared key to how participants perceived the study and their decisions about participation, including how decisions were made at the household. Provision of quality health care in the two case studies was easily the most commonly discussed expectation of the study and the main reason for joining the research. This is expected given the high quality health care provided to participants in most studies at the research centre, and to the wider population through boosting clinical services in localities of the studies (see 3.6). Related to expectation of health care was a belief for case study B that the vaccine was already working, what I called a research optimism. This was attributed to apparent low morbidity among participants due to good free clinical care offered in the trial. While this worked in that participants remained in the study, despite the worries and concerns they had, it leaves a lingering concern of potential for continued therapeutic misconceptions in future research, where participants might continuously associate research participation with personal health checks, and fail to consider research risks.

Worries and concerns about some of the study procedures were expected and informed through prior community engagement activities. What became apparent was that participants' perception of risks were not just about those related to the specific study, but also of being involved in KEMRI-WT activities. The latter included rumours associated with devil worship. Unfamiliar procedures seemed to build into these rumours initially, but were later challenged when there were no apparent adverse events. In part, this contributed to continuous surveillance of the research team by community members. As one PI informed me in one of our informal chats, if a serious adverse event unrelated to the study were to happen, it would take ages to rebuild trust in the community.

Household decision-making processes were generally described as complex and dynamic. In general, male household members, where present in the household, expected, and were expected to make research-related decisions as part of their normative gender roles as household heads. Research-related decisions included taking responsibility for research risks, including that of being involved in KEMRI-WT activities. Household consultations appeared to be a common practice for research-related decisions, and as a show of respect to household members. Where research decisions were likely to affect the normative gender role of women in the household, for example, as carers and nurturers of children, some felt that they needed to be more centrally involved in those decisions. Where this was not the case, some female participants took more pro-active roles, overtly or covertly, to influence the decisions to their favour; illustrating women's agency. This issue is revisited again with regards to silent refusals and research negotiations in 7.3.

For FWs at the interface of research implementation, they needed to be aware of and recognise the different factors underpinning research decisions, including hopes, fears and anxieties, in order to respond appropriately. These issues appeared to contribute to some of the challenges FWs faced in the two case studies, discussed in the next chapter (Chapter 7).

CHAPTER 7 A key FW role and challenge: negotiating research participation

7.1 Introduction

In Chapter 6, I describe participants' hopes, fears and anxieties, and household decision-making dynamics, as issues that appeared important in negotiations about research participation within the household, and with the FWs in the two case studies. In this chapter, I address the first part of objective 3: *To describe the main challenges faced by FWs in their interactions with community members*. The chapter is divided into two main sections: the challenges FWs faced at consent and at follow-up (7.2), and a description of silent refusals (7.3); a dilemma for FWs that emerged in this research. In the next chapter, I describe how FWs coped with and resolved these challenges.

Focussing on challenges could be seen as drawing attention to potential breaches of ethical guidelines. My intention is not to do this, but is to draw attention to the conflicts and tensions that arise from practice. As discussed in Chapter 4, both studies were reviewed and approved by local, national and international scientific and ethics review bodies; and had support systems in place to respond to emerging practical and ethical issues in the field. Focusing on interactions between FWs and research participants, however, highlighted the practical and ethical issues faced in research implementation, and how these are negotiated in practice.

By the time of collecting my data, the two studies were successful in participant recruitment and retention; with 47 (94%) households in case study A and 748 (83%) of

participants in case study B[61] retained. Initial challenges had been resolved, while others had emerged. Where challenges faced by FWs differed across the two case studies, I highlight this in this chapter.

7.2 Challenges FWs faced during consent processes and in retention of participants

While there were similarities in the type of challenges faced in the two case studies, there were differences in particularities in each case study (see Table 4.4 for case study information). In this section, I describe the particularities within the broad common theme.

7.2.1 Challenges at recruitment and in consenting

Low study acceptability

Initial recruitment rates in both case studies were reported to be slower than anticipated because of participants' apprehension of the study, and of KEMRI activities. For case study A, failure to recruit the required number of participants within the RSV epidemic would invalidate the study, or increase research costs through requiring extension to cover another epidemic season. These concerns worried FWs with responsibility for recruiting participants.

> "...that is something we had expected, that the acceptance rate might be low because of the complexity of the study given that we are targeting an entire household. So, expecting a household of 10, 20 sometimes 32 (members) to agree to a study... to get that common consent or common agreement to be in the study, that was the challenge" (R1, male, CSA/IDI01).

[61] The figure is cumulative of 75% in the 5-17months age-group and 95% in the 6-12 weeks age-group of participants in case study B who were participating in the study by the time of writing this thesis.

Low study acceptability contributed to a higher workload for FWs than was initially anticipated, and to both studies recruiting additional FWs to ease the workload.

> "...we were talking of 50 households, 50 looked like a small number because I thought a household will have 5 to 6 people. ...but basing first on the number of participants in the study, and then the number of samples that we get to deliver everyday to the labs, the frequency in which we are interacting with these participants, that makes the study very big..." (R2,female, CSA/IDI02).

For case study B, competitive recruitment across the eleven sites of the study, and the expectations of sponsors, put pressure on researchers and FWs to meet recruitment quotas within the agreed period.

Availability of potential participants for mutually agreed appointments

As described in 5.3.3, FWs roles included recruiting participants (both case studies) and undertaking consent processes (case study A). In homes, FWs reported feeling frustrated when potential participants missed appointments, as they had to make repeated visits, sometimes traversing across rugged terrain.

> "Another challenge was failing to get somebody at the time you have gone to their homes...we tried to schedule so that we get to households very early in the morning, but also that was difficult because you cannot get to someone's household when the owners are still asleep, like at 5.30am or 6.00am" (FW3, male, CSA/FGD05)

Challenges with information in consent forms in case study B

Terminologies and explanations of difficult concepts presented challenges to FWs; sometimes appearing to raise concerns among potential participants. Terms such as septicaemia, red blood cells, and plasmodium falciparum, which have no local translations were sometimes simply skipped.

"Like that disease of septicaemia... I mean how do you explain that when the (participant's) mother asks you 'blood cells, what is this disease about?' so they hear like it is blood cancer... when she probes further she confuses you; I mean she gives me a harder time in explaining to her than someone who knows a little bit (educated)..." (FW1, male CSB/FGD08)

Particularly problematic in case study B was translation of 'randomization' into '*pata potea*[62]' - a local lottery game of chance. *Pata potea* was expected to explain the likelihood of being assigned to the experimental vaccine (win) or the comparator vaccine (lose); however some participants understood it as a possibility of losing a child.

"... it was very difficult for people to understand (randomization) because they were saying that if it is not known which (vaccine) arm the child will be in... the child will definitely die because it is *pata potea* [game of chance]" (FW5 male CSB/FGD08).

Indicating some further difficulties with randomization, some parents only wanted their children in the experimental (malaria vaccine) arm because they believed it already worked.

"... the mother of the participant she knows that this is a malaria study and the child is supposed to get a malaria vaccine; and here you are telling the parent that there are other vaccines which maybe the child might get instead of the malaria vaccine. So sometimes it is not a case of misunderstanding, it's just a decision by the parent to want their child to get the malaria vaccine only..." (FW1, male, CSB/FGD08).

[62] A local game played similar to dice game; with animals drawn instead of numbers. The bet wins if the chosen face of the dice lands face up.

Related to concerns about *pata potea*, some participants interpreted *compensation* for adverse events (such as death) to imply a high possibility of death for participating children.

> "... there was a form (informed consent) which was written that if the child dies you will be given *fidia* (compensation) ... when my wife and I heard that there is *fidia,* she said I don't want (laughter)...if I give them my child and the child dies, then they give money that, will not bring my child back. We had to explain to her until she understood. And in fact, some refused at that stage when they heard of KEMRI giving *fidia,* they said 'we don't want our children in it. You want to take our child and give him/her to the devils'..." (Pax2 male CSB/FGD13)

Some participants wondered why they would be compensated for adverse events when they had 'voluntarily[63]' chosen to be in the study. For them, voluntariness implied acceptance of any outcome of the research. Others worried that accepting compensation in the event of an adverse event or death would ostracise them in the community for having joined a 'secret devil worship cult'

The *confidentiality* clause in the ICF appeared to cause apprehension amongst some participants; emphasising KEMRI-WT activities as shrouded in secrecy. They wondered why confidentiality was important when most people in their community knew of their research participation.

> "There is this part of confidentiality, the locking of documents in cupboards; sometimes when you explain that to your participants they wonder about it... it's like something will happen in the future which will surprise them, maybe the information that is kept in cupboards and in the computers, why does it have to be secret? So they didn't consider it as confidentiality for other people not to

[63] Voluntarism in this instance appeared to be relatable to giving services and resources for community development or assist the needy community members without expecting to be compensated for.

have access (to their information). They are surprised when you explain to them..." (FW4 male CSA/FGD05).

Information on volume and frequency of blood samples in case study B, as described in consent forms, was discussed at length during consent processes.

> "...so the issue of bleeding, linked to the information that they say that there are some rumours that they believe KEMRI is a devil worship organization, then they fear that issue of blood" (FW2, male CSB/FGD09).

These issues are not new or unique to this setting (see 3.6). Of interest is how information in a consent form can be pieced together to reinforce views and perceptions that the community have of the research centre. It was important for FWs and researchers to be aware of this, in order to find appropriate responses.

7.2.2 Challenges regarding who consents for the study

Household decision-making dynamics led to significant consultations at household level (see 6.3), and challenges for FWs in the case studies. Here I discuss challenges for FWs regarding who consents for research with regards to case study A and case study B, in turn.

Household level consent in case study A

For case study A, there were several challenges with entire household consent. Firstly, where the majority of household members consented but a few were reluctant or refused, the exclusion of that household appeared to favour the decision of the minority, which seemed unfair to some household members especially where the household head (HHH) had consented. In addition, FWs were worried that dropping such households would appear disrespectful to the household head.

"... the older people in the home consented to the study and it's the young girls who were refusing to be part of the study... it was the older people of the HH who were insisting that we continue (with the study)..." (R2 female CSA/IDI02)

Secondly, in some households, male household members resented participating in the study because NFS made them appear weak. The reflex tears produced made it look like they were crying, and the NFS was similar to cleaning nostrils of children. They felt they had done their duty of allowing the study into the household.

"One of them [household head] told me, 'I have already played my part in the study, I have given you all these people, so what else do you want from me? You don't have to do (swab me)', you know, so he feels like 'I have given you my household to do the swabbing so spare me'" (R2 female CSA/IDI02).

Thirdly, in households where the HHH was not the infant's parent, as was the case in many of the extended[64] households, a particular challenge for FWs was whose decision to consider when decisions differed. Being part of the community, FWs were aware that disrespecting a HHH's decision would not be well received in the family. FWs reported allowing time for household members to consult and being aware that the decision arrived at may be due to influence from 'significant' others in the household. Although this meant that the decision was not necessarily an individual's free will, they felt unable to prevent it from happening. This situation sometimes appeared to cause problems for FWs, such as being avoided in follow-up visits.

"...they both decided, I talked to the household head, he agreed; I talked to his 2 wives, first I talked to the first wife, she agreed and now she is the one who dodges..." (FW4 male CSA/FGD05).

[64] See also 3.5

Fourthly, FWs were worried that discordant research decisions may contribute to unanticipated household conflict, especially where minors and female household members dissented from the consent decision of males.

> "... this is one person (male household) who once he has made up his decision (for household participation), it is final. So, I think to that woman, she feels she can't change the decision the man has made [to consent]. Although during consenting of course they were all there, but I think simply because the man said yes, then the woman had to agree" (R2 female CSA/IDI02).

Finally, it was difficult to assent minors. There is a deep respect within many households across the community for parents and elders, such that children would find it difficult to contradict their parents' and elders' decisions and directives. Girls were reported to find it particularly difficult to express their opinions; it was difficult for minors to openly decline if that would cause the entire household to be dropped out of the study and, importantly, to miss out on the study benefits (discussed more below). Some FWs felt that minors' assent needed to be done appropriately, in a language that minors relate with, preferably away from their parents, but they recognised that it would require time that they did not have.

Case study B:parent/guardian proxy consent for a child

Case study B protocol stipulated that consent for a child's research participation should be obtained from both parents where possible. FWs worried that, where one parent consented, they would seem disrespectful if they insisted on seeking consent from the other parent (especially a mother), and that repeated home visits were a nuisance to the household. In some households where parents' decisions differed, FWs were requested by one parent to convince the other because the dissenting parent would find it difficult

to refuse a FW's request. It also appeared that some FWs expected a child's father to make a final decision and felt frustrated when this was not the case.

> ".... if the father really wants he can sign (consent form) before the mother and show that he has consented ... but you find he tells you he doesn't have a problem, the problem is the (child's) mother who goes to the dispensary. He then puts her in indecisiveness by asking her to decide (and then later) he asks her ... 'who told you to consent when I am not here? I didn't say that'. It becomes difficult, that's why mothers refuse..." (FW10, male, CSB/FGD08).

FWs reported feeling especially frustrated when mothers would not openly refuse to participate in the study, but would instead give different excuses, such as other appointments. One FW reported having followed-up a household eight times, even though the study provided a maximum of three follow-ups, as each time the mother seemed to have genuine reasons for needing more time, and the FW did not want to disappoint her. This issue is discussed later in 7.3.

In other instances, women consented to the child's participation in the study in defiance of her husband's decision, or without informing him, especially where the husband was not easily available for FWs to confirm research decisions. A case study B example is summarized in Figure 7.1.

Figure 7.1: Child enrolled in study without father being aware

In case study B, reported by a FW, a mother consented for her child to participate but concealed this decision from her husband for nearly 10 months, by which time the child had received the 3 vaccine doses and was waiting to receive the booster dose. The FW reported not being aware that the child's father had not consented as the man lived far away and rarely visited home. Consent for the child was given by his mother and grandmother, who is the household head as the grandfather was deceased. The child's father came to know of his child's participation in the research during a weekend follow-up in which he was at home. The fact that he had not been informed of his child's participation appeared to fuel existing marital problems. He sent away his wife (separated) after an altercation, blaming her for hiding things from him. The child's grandmother, a surrogate household head, and community leaders were invited to intervene and resolve the conflict. The FW felt that he could not intervene since he had all along believed that consent had been given by both parents. He also reported that the child's mother assumed that her mother-in-law, who consented the child, had informed her son while the mother-in-law expected her daughter-in-law to inform her husband. At the time of collecting my data, this issue had not been resolved: the child's mother had been chased away from her matrimonial home, and the child was withdrawn from the study pending resolution of the marital conflicts.

7.2.3 Challenges related to study follow-ups and retention

Beyond research consent, voluntary participation means that participants can withdraw from research at any time for their own reasons. Participants withdrawing from the research risk compromising validity of the research, and may lead to increased research costs and time lags. For longitudinal studies, various retention strategies are used to minimise loss to follow-up, including through withdrawals. For FWs, the challenge was how to respect participants' decisions while also being sensitive to study requirements. In this section, I describe challenges FWs faced at the data collection stage of the studies. Figure 7.2 summarizes an intense interaction I observed in the field between a fieldworker and a participating household in case study A.

Figure 7.2: Household-FW interactions: negotiating research participation

Imakando's[65] household was the largest in the study with about 33 members at the start of the study and 37 by the end (with two other women visibly pregnant). Nearly half of the household members were less than 15 years of age and in primary school. Tawanda, the eldest son in the family (who is also the surrogate HHH) is about 30 years[66] of age. His mother, Tebogo, is the first of Imakando's six wives and also a surrogate HHH in absence of Imakando; she appeared to be about sixty years old. Imakando himself lives about 100 kms away with another set of three younger wives and about 40 children and grandchildren. There are 8 nuclear families living in the study HH compound, all of whom are Mzee Imakando's immediate family (three wives, children and grandchildren). All the houses are mud-walled, makuti-thatched, and rather dilapidated huts, with some apparently about to collapse; many huts did not have doors.

Imakando's household presented a unique opportunity for CSA researchers to study RSV transmission patterns. Researchers were keen to retain the household throughout the study period; a point regularly emphasized in study team meetings and in the frequent PI visits to the household.

Rutendo, the FW assigned to follow-up the household, found it particularly challenging to work with so many participants, and usually allocated an entire day to collect data and respond to emerging issues in the household. On this particular visit, we arrived at the household at the usual time of 8am to find Tawanda and most of the other men seated outside one of the huts drinking local brew (mnazi) while the women were pounding maize nearby. After greetings, we were directed to a place far from the men which Tawanda had instructed the women to prepare for us. As soon as we arrived, many children (I counted 8 children under 5 years old) surrounded us. Rutendo collected the illness history for all HH members, the temperature and respiratory rates of children under 5 years, and then took the oral flocked (OF) swabs from all HH members. Throughout this period, he chatted with household members. I assisted him, wherever possible, to record information.

Collecting the NFS was the most challenging task for Rutendo. Most HH members, especially women and children, were reluctant. Some refused, others hid, while others still vehemently protested. At one point, a group of women appeared to gang up against Rutendo, demanding to be compensated with cash for each NFS taken. Then later they refused the NFS unless the results of the previous samples were given. When they eventually did agree, most were fearful; flinching and complaining bitterly. Some women also were reluctant for their children and infants to be taken NFS. Many only complied when the FW threatened to drop the household from the study, and withdraw the clinic card enabling them to access the free health care benefits provided by the study. Rutendo referred to the information contained in the informed consent to explain why participants could not get individual cash benefits, and to clarify the study risks (that the study was relatively safe). The men seemed to listen keenly to these conversations, and generally gave research data and samples without much fuss. Several times, Tawanda and Tebogo commanded the women to respect Rutendo, but these instructions were

[65] All the names used in this illustrative case are not the real names of the people involved. Some of the details of the household and of the FW have been changed to preserve anonymity. However, details of the interactions reflect the real events that I observed in the field.

[66] Approximate age based on the national identity card details. Most household members (apart from his mother and her two co-wives in this household) seemed to be in their early to mid-twenties.

obeyed only momentarily, before the women started arguing with Rutendo again.

Rutendo was initially quite calm, but as these arguments continued, he sometimes got annoyed or tried to seek my help and support. He frequently reminded everybody that participation was voluntary; that they all just needed to all agree to withdraw and he would inform his bosses. In those moments, some household members would grudgingly agree to the NFS. By the end of the visit, Rutendo sounded keen for the researchers to drop the HH, or to hand it over to another FW. Later I learned that the PIs visited the household and discussed some of the issues raised by the participants. They also 'quietly exempted' some household members (those most distant from the index child) from the NFS. When I visited the household again during the exit of CSA, everybody seemed to have become familiar with the study procedures, and hardly complained at all. They even requested for the study to be extended, albeit with less frequent taking NFS. Witnessing the intense negotiations that happened during this one interaction made me so aware of the complex and morally imbued roles FWs played in the field, and the continuous negotiations between households and FWs.

Participants' changing decisions about continued participation

Consenting for study participation means there is an implicit obligation for participants to adhere to follow-up activities and to inform FWs (and researchers) if they wish to withdraw from research. However, FWs often needed to countercheck whether participants were still happy to stay in the study, especially where they seemed reluctant. Participants wishing to withdraw presented challenges for FWs when that decision was not verbally communicated, or when such a decision appeared to conflict with those of others wanting to remain in the study, as discussed in 7.3.

Threats to male FWs, and the study interfering with household arrangements

Research participation also appeared to bring out more openly what were likely to be simmering tensions within a household. In these cases, FWs found they were embroiled in domestic disputes because home follow-ups provided social spaces for interactions. Incidents of male FWs being threatened by spouses of female participants were narrated in both case studies, with hints that the male spouses were jealous of FWs' employment in KEMRI-WT and of the steady 'high salary' they earned. Some research responsibilities such as being polite and caring attitude towards participants, the

provision of meals and transport in case study B, and the monitoring of wellbeing for participants in both case studies seemed to exacerbate these concerns. This is because such behaviours are ideally supposed to be husband's duties and responsibilities for their wives and children. In a few households, such tensions contributed to some mothers withdrawing from the study (see below).

Delay in study benefits and worries of loss of trust for FWs

Some participants argued for more benefits for their participation. For example, some parents demanded for maternal services[67] in case study A, and male-child circumcision services in case study B. Some women threatened to withdraw and incite others to refuse the studies if these services were not provided. Long lists of community needs were presented at community engagement meetings. While researchers' and FWs' general response was to emphasize what research and the specific study was about, FWs empathised with these demands because they understood these as real needs in the community (see also 9.3.2).

Resistance of study procedures and uncooperative participants

Resistance to study procedures (and to the research) took different forms including dodging FW visits, use of derogatory terms to refer to the study and to the FWs, continuously negotiating for changes in study procedures, and negotiating for additional benefits to compensate for study inconveniences. 'Uncooperative' or 'difficult' participants were some of the terms FWs used to refer to reluctant participants.

[67] Prenatal and antenatal services are ideally provided free at the public health facilities, however mothers attending these services often queue for long. They also pay referral costs in case of complications.

"I had been there many times ... there was one household which was a problem to me because every time we went there the father will pretend to be very busy (*others laugh*), even if he is seated outside the house. ...the moment he sees you, he wakes up and gets an exercise book and tells you 'please am very busy'" (FW3, female, CSA/FGD07)

"...it was a difficult household...today they will accept (for data to be collected), tomorrow they are saying 'we want a rest'..." (FW4, male, CSA/FGD07)

FWs were expected to withdraw reluctant participants from the study, but, as discussed below, these choices caused further dilemmas for FWs. A particular challenge for FWs, at both recruitment and follow-up stages, was in handling participants they referred to as 'difficult' or silent refusals; I discuss these next.

7.3 Silent refusals

The previous section described multiple and multi-layered challenges FWs faced at recruitment, consenting and follow-up phases in the two case studies. A particular dilemma, that FWs faced constantly was in handling participants who participated inconsistently, or in some study procedures and not in others, without openly refusing or withdrawing from the study; a form of 'silent refusal'.

"... but the way they were telling you is that, even you (FW) go in the morning and you tell them (participants) 'the vehicle is coming, prepare yourself' ...and she tells you 'there is no problem'. ... and you go there with the vehicle, and when you arrive there she says 'aaah I have remembered that I have a visitor, I'm now going out so I will also not come to the dispensary'" (FW1, male, CSB/FGD10).

"...so he (the participant) is around the house, so when you tell him it is now his turn (to take NFS) he tells you he is too busy, come back later...like noon or

1pm, but when you go at that time, there is no one, he has left" (FW4, male, CSA/FGD06).

Such participants appeared to have credible reasons for inconsistent participation, and in the first instance FWs would not know that they were reluctant to participate.

"If you go (follow her) she gives you reasons which are understandable. Because she says 'today my children have no food, so I will have to go and look for farm work" (FW4, male, CSB/FGD10).

"... if the parent has failed for the first and second time, and when she is visited at home and is reminded she says 'ok, I will come, just go', even if a car has gone to pick that parent, but she says to the KEMRI staff, 'just go, I will walk', then know it is a silent refusal" (Pax1, male, CSB/FGD13).

FWs could generally discern a silent refusal over time, having known the person well, as was pointed out by a FW using a popular Kiswahili proverb.

"...I have truly known that *akufukuzae hakwambii toka* (the one who chases you does not tell you go)... So it's normal that it is not every time someone tells you 'I don't want' [to participate in research], you have to understand them according to their actions or words then you completely know that this person does not want to participate" (FW1, male, CSA/FGD05).

"... if you are told that, be ready tomorrow at a certain time, you will be picked, but when the FW comes to the home, the mother is away ... So that shows that the mother wants to withdraw but she doesn't want to out rightly say so" (Pax2 female CSB/FGD12).

7.3.1 Why silently refuse?

Based on discussions with participants, researchers and FWs, the reasons for silent refusals in the two case studies appeared to fall under three broad categories: those

related to relationships with significant others including FWs, avoiding conflicts in the household, and those related to study specific activities and concerns about KEMRI-WT. I describe these in turn.

Safeguarding relationships with FWs and with KEMRI-WT

Silent refusal was described as an appropriate approach in situations where one was uncertain or wanted to be given time to weigh up options before making a decision. Not openly refusing a request was described as an investment in future situations where one might require assistance.

> "... so you don't want to refuse someone's request because it's like you are *unaweka akiba* (investing) so that another day someone will be kind to you" (FW3 male CSA/FGD06).

Some participants found it difficult to refuse FWs' request to join the study because they did not want to appear rude, and were still weighing out what it meant to be involved in research and in KEMRI-WT activities. They worried that requesting for additional time to make these decisions might be understood to be a polite way of refusing the study. Friendships and positive relations between FWs and participants that developed (discussed in 8.4) also facilitated the emergence of silent refusals.

> "You see, silent refusal usually happened because someone sees like you have become a member of that family; you have become part of them. So, they start to blame themselves because you have that *uhusiano* (good relationship) between you and her. So she feels if she tells you openly that…'from now or from today I withdraw'...she feels guilty that 'this person has been like my child, has been like my grandchild, or has been like my uncle or has been like a brother, so when now I withdraw its like I will be chasing them away... So that is why you see them not showing the signs of wanting to withdraw" (FW1, male, CSA/FGD06).

FWs, being community members themselves, might also have contributed to silent refusals because of an expectation from community members to help one another. They were seen as being in a position to help other people, including the participants. Some participants then worried that by refusing the research, FWs might also refuse to help them when in need.

> "Somebody like me, I'm respected in the community. So, somebody coming to me and telling me that I don't want that (study) is hard. So he takes you round, like the saying 'the one who chases you doesn't tell you go away', so its upon you to understand that...aah 'I have been taken round [given many excuses], this person doesn't want'; but her herself, because she is respecting you, she can't tell you no" (FW5 male CSB/FGD10).

Other participants were worried that KEMRI-WT had such great influence in the provision of health care in public health facilities that if they refused to participate in research, they would be denied health care.

> "...another one is that one knows KEMRI has a branch here (at the dispensary). So they know that and they fear that 'if I say I don't want KEMRI here and they are here (and) if my child or I become sick and I go there (at the dispensary) and I had refused KEMRI (research), then I may be denied services'" (FW2, male CSB/FGD10).

Other participants may have consented to the study due to pressure from peers, friends, and community leaders, and not because of their own choice; dodging the study team during follow-up periods was a way to get out of a decision they never intended to make in the first instance. Others may have been dissuaded by rumours of KEMRI, fears of blood sample taking and concerns about study and vaccine safety. For them, silent refusal was a polite way of refusing a study they did not quite understand, and to do so in a way that did not offend the FWs.

Avoiding conflicts within households

i) Silent refusing masking genuine refusal

Silent refusal also appeared to be a strategy to avoid tensions and conflicts between couples/parents and within households. Some participants who did not want to openly oppose or defy others' decisions, particularly those of elders and HHHs, preferred to be silent refusals. Here, genuine refusal was masked because of worries that making it obvious would strain relationships in the household; being silent safeguarded short-term harmony at home.

> "... So the thing is if like that one (a silent refusal), he could not out rightly say that he had withdrawn because he is not the household head, his elder brother [the HHH] fully participates in the study. And then he is the first person I talked to and he agreed and then the rest joined... So I think he used to think that the moment he says that he does not want [to continue with participation]...the rest will be dropped as per the study protocol, so he was afraid of something like that, so that is why he used to hide" (FW4 male CSA/FGD06).

As discussed in 6.3.3, male participants were aware that their wives used silent refusal to defy decisions they were not happy with; but they felt unable to do anything about their wives' actions, blaming women for not understanding the 'health care' assistance provided by KEMRI-WT.

> "Yes, as the husband you can consent, and the wife can go as if going to the dispensary and because of ignorance (not knowing) you can be saying the child has been sent (to the dispensary)... but in fact he has not been enrolled in the study. And if she comes to the dispensary, she does other things. So because of that they (study researchers) keep waiting for her and they get tired (drop-out the child)... Now, they (decliners) are saying that they missed good things..." (Pax6 male CSB/FGD13)

ii) Silent refusal masking research participation: 'silent participation'

Linked to 'unpopular male decisions', some participants appeared to behave like silent refusals in order to mask their participation in research because they had earlier defied decisions of others (especially husbands and male HHHs) and 'covertly' consented to the research. They viewed the dissenters' decisions as based on 'unfounded' fears towards KEMRI-WT and its research, and hoped these dissenters would relent over time. The extent to which FWs were aware of this, and even encouraged such participation was difficult to know. However, that it happened, albeit in only a few cases, is a point of concern for informed consent.

> "Maybe the vehicle goes to pick her...when the father is around, he refuses the mother from going to the dispensary. But when the husband is not around and they (FWs) have gone to her, she comes to the dispensary" (Pax9, male, CSB/FGD13).

Some female participants were especially careful about being associated with the study and male FWs because of their husbands' jealousy towards male FWs, as earlier described (7.2.3). Silently participating in the research, while pretending to dissent when the husband was around, was one way to mask research participation. The most common reason given for women lying about research participation was that being in the study was the only they could access, and be assured of, free high quality health care for their children.

iii) Silent refusal: resistance against 'unpopular' study decision

As described in 6.3, decisions about household and children participation in research were often made by male household members, even where consultations did happen. Where responsibility for research follow-up affected normative gender roles (such as women taking children to health facilities), those most affected by participation wanted

to be actively involved in decision-making, which did not always happen. One of the tactics used by those neglected, especially women and mothers, was to silently defy decisions taken by others where they felt strongly that their opinions mattered. As a mother narrated in an FGD, women would only enrol their children in the study if they have made that decision, otherwise they would use tactics to dodge participation.

> "...the mother is the one who will get hold of the child as blood is being drawn from the child. If the father agrees for the child to participate but if the mother refuses then you (mother) won't send the child. You may go and stay outside and then go back (home) with your child and say the child has missed the vaccines or you say the child has been attended; but you will just be cheating. ...that's why you will hold the child during bleeding, you look at her as she cries, but you will only do so if you have decided; but if not, then you will come back with the child" (Pax2, female CSB/FGD12).

Study related concerns: not wanting to lose study benefits

Study benefits formed one of the most common reasons for research participation in both studies. Fear of loss of study benefits made some participants reluctant to drop-out of the studies. Participating in some procedures and not in others, and some times and not in others, appeared to be a strategy by participants to access full study benefits while choosing how and when they participated in the research. This approach seemed to be supported by some FWs who were aware that study benefits filled a livelihood need, especially for the extremely poor households; allowing silent refusals to remain in the study was one way of helping these families. The flipside for FWs was that accommodating silent refusals was likely to encourage other participants to behave similarly; this would lower the quality of data.

> "Another thing also, I think these health services or medical services also contributed because someone thinks that maybe if they do not want and they say that openly that they do not want and the way it is said that if one person

withdraws that family is ineligible. So that person dodges. They do not want to say the truth because they think if they say 'am withdrawing' then the whole family is ineligible so they run away..." (Pax5, male, CSA/FGD06).

7.3.2 FWs' dilemmas in handling silent refusals

For FWs and researchers, it was important to understand the reasons behind silent refusals to know how to address these. Some FWs felt frustrated with silent refusals because of the increased workload in having to repeatedly follow them. FWs also were sometimes blamed by researchers for having caused a rift with the participants, leading to the inconsistent participation.

"... and the (study) coordinators say that if somebody is there (present), you try your best to make sure that person is taken samples, so you have to struggle to get that participant. You might go to a household and find that there are others running away....you are therefore forced to follow-up maybe today you go and miss him, the next day you miss him too until when you eventually get him its even past 9pm...you might find him because you went there (home) abruptly... Its becoming difficult" (FW2, male, CSA/FGD05).

"... so that is the problem for us (FWs) having pressure here, it's better if you didn't consent the person in the study but you consented them, she is in the study and then she withdraws or she has gotten one dose (of vaccine); its better if that person had relocated to another area, there would be no problem. But you know she is there (at home) and she doesn't want to tell you (why she is reluctant) and then when you reach here (office) there is pressure you are being asked, 'what have you done to this child? What have you done to the mother until she now wants to withdraw from the study?' So the pressure comes to us (FWs) without us wanting it by being asked by the different bosses who want us to explain... if you say she is there (at home) but you don't understand why she dodges, you are being told no...us as fieldworkers we are usually under pressure" (FW1, male, CSB/FGD10).

The dilemma for FWs with silent refusals was whether to accept it was a refusal and drop them from the study or retain them in the study. The problem with this approach was that some participants were comfortable with some of the procedures (and not others), and would have been annoyed to know that they had been dropped, and this would have made the relationships between them and the FW more strained. This was likely to be awkward if FWs continued to follow up other participants in the same household. A related concern was that dropping the participant would have meant that they could no longer access the study benefits, an issue FWs struggled with especially for the poor households. In addition, participants appeared to get used to the study procedures over time, a FW deciding to drop a participant early on might later be blamed by that participant. Finally, FWs were part of the community members, the study was simply a transient activity that should not mire established relationships in the community.

7.4 Chapter Conclusion

In this chapter, the multiple challenges that FWs faced during participant recruitment and consent; and at follow-up activities (data collection) were described. The types of challenges FWs faced ranged from practical ones such as workload distribution, provision of work equipment and space; through technical challenges such as competence in relaying consent information and in carrying out study procedures; and ethical challenges such as handling of discordant decisions at household level, and of silent refusals.

Undertaking consent processes as per protocol, the amount of information in the ICF, the translation of difficult terminologies, and household decision-making dynamics

presented particular challenges for FWs. Getting consensus on household decisions (case study A) and for children's research participation (case study B) required FWs to be aware of and respond to household dynamics including intra-household tensions. For FWs, balancing research protocol requirements, cultural norms and household decision-making dynamics, and their own interests of keeping the job through good performance, presented dilemmas; exacerbated by their being members of the community with knowledge of culturally acceptable behaviour of social interactions.

A feature of participant-FW interactions emerging from these findings is that – in these case studies - research participation was continuously negotiated throughout the course of research. Consent decisions were informed by several factors including perceptions of what the study will provide (expectations of study benefits), responsibility for research participation, the nature of relationships and influence of 'significant others', and the extent to which individuals could negotiate favourable conditions for their participation. Research was happening in the lived social world of participants; decisions were not just about weighing up research importance, risks and benefits, but also about safeguarding important relations with significant others. FWs at the interface often faced complex situations that were not always fully articulated in SOPs and in ethical guidelines, and were having to balance ethical requirements and culturally acceptable behaviours.

Silent refusal emerged as a particular dilemma for FWs. Silent refusal highlight the interweaving of relationships in research conduct and shows the way those otherwise assumed to be 'powerless' exercise their power in unequal relationships; wives making decisions about areas they would otherwise not be expected to control; and participants

determining how to participate in research. It also shows the vulnerable positions of the otherwise assumed powerful. This issue is revisited in 9.3.3.

Having described the type and range of challenges FWs faced in the two case studies, in the next chapter, I discuss the attempts made to resolve these issues by the FWs, the study team and the research programme, including the ways in which FWs negotiated tensions between ethical requirements and cultural norms.

CHAPTER 8 Coping strategies FWs used: the centrality of social relations

8.1 Introduction

In Chapter 7, I described the main challenges that FWs faced at recruitment, consent and in the follow-up phases of the two case studies. In this chapter, I address the second part of objective 3*: To describe how challenges faced by FW were resolved* and the fourth objective of this study: *To describe emerging dilemmas for FWs in their interactions with participants, including those associated with silent refusals, levels of benefits and the development of social relations*. The chapter has four sections:

- an overview of the strategies FWs used to resolve challenges that were discussed in Chapter 6 and Chapter 7, (8.2);
- illustrations of the centrality of study benefits and social relations in research negotiations, and of the ethical challenges and dilemmas they presented to FWs and the study team (8.3 and 8.4); and
- the support systems available to and used by FWs in their coping strategies, and factors influencing their use (8.5).

I use the term coping strategy to imply going beyond the normal course of action. This has two further meanings. Firstly, a problem is anticipated and there is a planned course of action, however the context under which the problem occurs means that other alternatives need to be considered. Secondly, I use it to refer to an unanticipated problem with no simple solution. Not all strategies used by FWs were coping strategies; a difference I have tried to draw out where necessary.

8.2 Coping strategies used by FWs

Strategies used by FWs and study teams to cope with the challenges they faced can be grouped into informational strategies; convincing and persuading participants; and allowing participants time to get used to the study procedures. I discuss these three strategies in turn.

8.2.1 Informational strategies

Informational strategies included seeking acceptance and permission for regular follow-ups with participants in out-of-office time, and addressing the numerous questions about KEMRI-WT and the studies. While these appear to be part of the formal roles for FW, FWs were often going an extra mile, as will be seen.

Seeking acceptance and permission for study processes

FWs said that being polite and respectful to participants, and carefully explaining the nature of their work and why it was necessary to repeatedly follow-up participants, was essential for avoiding conflicts and gaining acceptance at households.

> "I talk to them, I make sure they understand that I am going to disturb or interfere with their schedule; (that) I want to follow up this child at home because this is part of my work. I can't follow them at school or by the road and do this thing [take NFS] because whoever sees me dealing with a kid, and of course the child will cry, how will they take me?...so I will disturb you somehow if possible. And then they will think about it and they will just say, 'okay it's alright you can come'" (FW3, male, CSA/FGD05).

Involving the entire household at the outset was important to gain support for research participation, and for FWs' permission to regularly visit the household. The latter was especially important for male FWs to avoid being misunderstood when interacting with female household members.

Following-up participants in out-of-office hours

The majority of FWs in both case studies reported following up participants in out-of-office hours to discuss the study, especially for participants who were fearful of study procedures, or whose parents were often away. The extent to which this took place, especially for case study A, was not expected. FWs felt that out-of-office follow-ups allowed for deeper discussion at convenient times for participants, and went beyond mechanistic conducting of study procedures and following of study protocol, to developing friendships that mattered for the success of the study, as discussed in more detail in 8.4.

> "...during my first visit there I found it very difficult because the children were refusing to be sampled (taken NFS)... I used my common sense, I befriended the mum. That day I was there I made sure I assisted in making *makuti* [coconut-thatching materials] and we chatted... for those 2 hours I was there, and by the time I left we had become friends. During my next visits I befriended the children, I gave them more sweets than they used to be given (by the previous FW) and by the time we finished taking samples from the household, they had accepted me ... I even used to take lunch (at their home)... Their grand mum was not in the study but she was a very good friend to me. Even now when she comes here at the dispensary, she makes sure she see me and greets me and she shares with me any problem she has, and I assist her, and the mum. Now she is one of my very best friends, (FW3 female CSA/FGD07).

Addressing numerous questions about the study, and of KEMRI-WT

FWs were, as expected, having to continuously clarify difficult concepts such as randomization, and explain unfamiliar or disliked procedures. Some FWs were frustrated that participants kept asking similar questions over repeated visits, many of which had been answered in previous encounters. Repeat questions were attributed not only to difficulties in understanding the research concepts and participation

requirements, but also to participants assessing consistency and trustworthiness of FWs.

> "In fact, as my friend FW5 has said, that consenting is a process, it really is a process; because you can explain something to them (participants) then after like 3 days 4 days they forget, they again ask you about results, you explain to them and after 3 to 4 days they ask you...the same, same question you explain to them... So, you keep explaining to them the same thing and they forget after sometime" (FW4, male, CSA/FGD05).

Continuous counter-checking of information provided by FWs also appeared to point to unsatisfactory responses and anxieties about KEMRI-WT's work. For example, I observed that requests for individual test results dominated discussions during study encounters in case study A, and at exit of the study, despite participants being informed that results would not be available because these would not have a bearing on individuals people's health.

8.2.2 Convincing and persuading participants about the study

In interviews with FWs[68], the boundary between giving information to allow for participant choice, and over-emphasizing the positive elements of the study, appeared blurred. FWs used words or phrases such as *convince, reassure, ask them to persevere, use sweet words, and plead*, to describe information sharing with participants.

> ...where the mother and the father are not cooperative, you end up spending a lot of time convincing them, or you try to convince the other participants... (FW2, male, CSA/FGD05).

[68] All FW interviews, except one, were conducted in English

> ...because they (participants) do not want their nostril to be swabbed [NFS], we used to talk to them so that at least they can be taken the oral swab that is taken once per week, we pleaded with them..., FW4, male CSA/FGD06).

> ...so then we had to go back again to plead with them, we tell them sweet words and we told them the truth as to why we are continuing (with the study) until June.... So in my opinion, we exceedingly succeeded (in retaining the participants) (FW1, male, CSA/FGD06).

These words were often used without deeper reflection of the possible implications for ethical conduct of research. Where FWs were aiming to convince participants to persevere with the study this may have been so participants could continue to access health care benefits, as discussed more below. FWs presumably also felt under pressure from supervisor or PI to recruit and retain enough participants in the study, as described in 8.5.2. FWs appeared to use two main approaches to persuade participants to consent and remain in the study: reference to the ICF, and to other people.

FWs often described *referring to the ICF* to remind participants of their obligations in the research; something I also observed in the field with FWs where participants raised many questions.

> "So now I always want to go to the idea of consenting, I always have to reassure these guys that this has to be the way. Otherwise if you drop out of this (study) we wouldn't have done you any good because we will not have answered our study questions and then we will have just disturbed you for nothing. At least they understand" (FW5, male, CSA/FGD05).

Regarding reference to others, for difficult-to-get participants such as silent refusals, FWs consulted family members, opinion leaders such as the CHWs, village elders and

study team members, and sometimes involved them in resolving issues. In one extreme case where a woman wanted to withdraw from case study A, her husband wondered whether he could force his wife to continue with participation. While the FW refused to agree to this, that the man wanted to use this measure illustrates the need for researchers and FWs to be aware of complex and gendered decision-making dynamics for research within households.

> "...I even can't tell [why his wife was refusing]. I asked the husband whether there were some quarrels, he said no... he went to the extent that he wanted to grab her (his wife) so that I can take the samples, but then I said 'no, don't grab her'", (FW4, male CSA/FGD06).

The 'best performing'[69] FW in case study B said that requesting other participants in the household to persuade a fellow household member worked well because the information they shared was based on experiences of having participated in the study. Also, community members tended to trust each other more than they would a FW who would most likely be interested in meeting study targets.

> "...participants understand the project. When they have understood the project, they help me to look for other participants, you see ... a participant is the one who will consent their colleagues, because when you explain to them they will say they are busy ... [and] that you are working, that is why you are talking good, you are working", (FW1, male, CSB/IDI07).

FWs also reported involving their seniors (SFW and researchers) where they encountered difficult and adamant participants. While this was in line with study protocol, it could also have been perceived as additional pressure on participants to join or stay in the study.

[69] The FW had the highest number of participants in both groups of participants, PIs praised him for working hard, was often called on by other research team members (clinicians, other FWs and the PI), to give study information to 'difficult' participants or those who had numerous questions.

"...So I told my bosses, one of my bosses went there, she tried but she didn't succeed [to talk to participant]. She (participant) told her 'I am not okay with giving the samples'; so I had to use her (participant's) husband to talk to her. She is now giving only oral fluids and she sometimes refuses her children from participating in the study. So, when she is not there, you will (get) samples from her daughters and the sons but if she is present they refuse", (FW4, male, CSA/FGD05).

Implications of persuasion on the ethical conduct of research

Two issues emerged with regards to *persuading* participants to remain in the studies: defining persuasion; and balancing voluntariness against study validity.

Complexity in teasing out persuasion

Distinguishing persuasion and information giving depends on the nature of conversation and interaction, including what words are used and how. Nevertheless, there were several FW descriptions of handling 'difficult' participants that are clear distortions of study information, including clearly exaggerated ancillary care benefits, or exaggerating risks of not participating consistently. Such examples are ethically important.

"....initially there is another lady that was not verbally telling me that she didn't want to participate but was always escaping....I tried to talk to her and explained the importance of that (NFS). I said '...you are a lady who always interacts with the infant, this (NFS) is painful but this disease is harmful, it will even kill the child or even destroy some things in the system of the kid. So what do you think is worse, running away from me just because of the little pain and the discomfort of the nasopharyngeal swab, or losing the kid?' So it's like she came to understand the importance of the sample collection, and up to date I am taking samples from that woman," (FW3, male, CSA/FGD05).

FWs might not have been aware of the ethical implications of exaggerating benefits. They appeared to struggle with the boundary between sharing unbiased study information for understanding and being sensitive to the health care needs of the community that were provided for in the study.

> "...I told them that the children have a high chance of getting the malaria vaccine. And also that this meningitis vaccine is very important because if we consider; the anti-rabies vaccine is very expensive; if you are bitten by a dog at this time and go to the hospital, it is very expensive; it costs almost Ksh.10,000 [70] to be vaccinated. If your child gets that anti-rabies (in the study) he will have benefited," (FW3, male, CSB/9).

Voluntary participation versus study validity, the dilemma

Retention strategies for the two case studies (4.3.2), especially provision of health care, could also have made it difficult for some participants to withdraw from the research, in the context of vast unmet health care needs (3.3). Ensuring that study benefits are not so high that they unduly influence participants (allowing participants free will to make decisions), while motivating participants to stay in studies, is a balancing act that presented dilemmas to researchers and FWs, especially in entire HH studies.

> "...the ICF states they (participants) are free to participate and at the same time even if they are in the study they can even withdraw at any time, and there is nothing that is going to affect them, they are free. It's only that according to our research if somebody in a family withdraws and somebody else in the same, same family wants to participate; now it becomes complicated, so we have to go and convince that person, explain each and everything to them. Still they have to understand that the moment they withdraw from the study, the (research) question won't be answered and then they will not get the benefits...it will be a loss to the household members who are willing (to remain in study). So we consider these two (issues); and then if it were not for such types of studies,

[70] Equivalent of $125 at the exchange rate at $1 = Ksh.80 as of 2011. Though rarely available at public hospital, the actual cost is $3.for 3 pre-exposure doses.

then we wouldn't have drugs today and some other things (like) measles vaccines" (FW3, male, CSA/FGD05).

"...you should also remind them (participants) that this (participation) is voluntary, but also that is the point when you want your number of samples to add up and you also feel like you want these other guys (FWs) to push (convince) this person to have the samples collected. But at the back of your mind you know that is the time you should actually tell them: 'remember it's voluntary, I don't want to force you to do it'....but the more you say it's voluntary, your numbers will not add up and probably your study will not go as you wanted. That does not mean that it is not data in itself...," (R2, female, CSA/IDI05).

As a compromise, researchers apparently allowed some flexibility in some study procedures (such as taking shallow NFS initially) and in participation requirements (such as allowing silent refusals). But this approach introduced worries about the quality of the data. Keeping the flexibilities quiet facilitated researchers to retain the required number of participants while also allowing participants to get used to the procedures.

"...but he (PI) said just for the sake of those people [who are fearful of NFS] let them do a shallow swab...that will keep them accepting the swab and that will assist to also keep the other participants who are not very fearful to continue accepting the swab...," (R2, female, CSA/IDI05).

"...other participants could only do a shallow swab (NFS) then we had to maintain those [by allowing it]. In one household, a participant was able to swab herself then and in fact before we allowed that, we visited and we ascertained they were collecting the right swab," (R1, male, CSA/IDI04).

8.2.3 Allowing participants to get used to study procedures over time

Encouraging participants to stay in the study, and reassuring them that over time it becomes easier, were frequently reported strategies, as was encouraging participants to talk through their worries and anxieties.

> "...I started to open up a discussion with her. I asked her 'why do you always run away?' and she also opened up and told me 'I always hear these young kids crying whenever you are doing your procedures'. So now, I told her, 'okay fine if that is the problem then can we take only the oral fluid, could you try that?' She said 'ok coz that one doesn't make anyone cry; I think I can be able to do that'... So I went back there at around 6am, very early in the morning and when I offered the OF (oral flock swab) to her she took it. And when I asked her 'what do you feel about it?' she said it's not painful. I asked her 'would you also try the nasal sampling (NFS)?' she said yea let me try and just agreed...," (FW5, male, CSA/FGD05).

Over time, FWs reported facing fewer challenges as familiarity grew.

> "...but as we continued, someone would think, 'ahh now I am afraid but a small child is being taken samples without any problems, let me also try'. And when they try they find it is fine. So that getting familiar with the people simplified the procedures till we had no further challenges, (challenges) became fewer and fewer till we completed the study very well" (FW3, male, CSA/FGD06).

8.2.4 Handling silent refusals

Study team handling of silent refusals

Protocols in both case studies provided that a particular participant is followed up to a maximum of three times, after which he/she is considered a refusal and dropped from the study. Case study B protocol provided that a follow-up visit is made to those who withdraw from the study to find out the reasons, as that could provide important considerations should the vaccine be licensed. Consent forms clearly stated that

participation is voluntary and that a participant can withdraw at any time without censure, and will continue receiving health care services as they would normally.

Each study also had a minimum number of participants required if it was to be scientifically valid. Recruitment rates allowed for dropouts and withdrawals. When faced with silent refusals, FWs and researchers initially followed study protocol and dropped participants from the study. However, as described above, FWs needed time to reassure participants, build trust, and communicate with others in the home. The positive relationships between the participants and the FWs, and potential mutual benefits of silent refusals (see 7.3) safeguarded against hasty decisions.

Over time, the study team accepted some silent refusals as 'permanent' within a participating household if the individual who was repeatedly 'not available' had minimal contact with the index child.

> "...we accommodated those who rarely get in to contact with the infant...whenever we did our home visits, we would collect data on their illness history... I would say they were not actually refusals of study participation, it's refusals to be swabbed [taken the NFS] period; but they were happy to be in the study...", (R1 male CSA/IDI04).

Participants' views on how study teams should handle silent refusals

In interviews with both men and women participants in the two case studies, they suggested that FWs should find out underlying reasons for silent refusals and ways to resolve them. The suggested solutions included providing more information about the study, clearing up any misunderstandings about the research and KEMRI-WT's work,

and explaining what is expected of the participant. Only one participant suggested that those reluctant to participate in research should be left alone.

> "...if every time I fail to get the mother at home [because she dodges], then I will want to know the reason, whether she is willing to participate or not" (Pax9, female, CSB/FGD12).

Strategies suggested to handle silent refusals differed between men and women participants, because household decision-making for research is a gendered issue (see 6.3). While female participants felt that community leaders such as village elders and chiefs should arbitrate between FWs and silent refusals, male participants suggested that arbitration may seem like being challenged for their decisions, and advised against it.

> "In their misunderstanding they think if they go to the village elder they have been sued for a mistake they have done. Instead of them knowing that they are being assisted with their children getting treatment they think they are going to be arrested. So these advices we are getting here, if he is called by the village elder he will think he's been sued...," (Pax1 male CSB/FGD15).

Those suggesting arbitration appeared to base it on wanting to support participants' access to health care, arguably a misunderstanding on what research is and how it differs with treatment, and the place for personal choices in research.

8.3 Incorporating study benefits into negotiations: common but contested

In interviews with study participants and study team members, the levels of benefits, especially health care, and the respectful way staff handled participants were described positively as having contributed to consent and retention in the study.

"...that getting of (health care) services, being followed at home with a car, taken to hospital, receiving free (treatment) at the hospital, being taken back home...that is why many of them don't want to go, because of the care by KEMRI" (Pax3, male, CSB/FGD13).

"...we easily accepted (consented) because when you reach at the hospital (local dispensary) you get the *huduma* [service]. And if the child is very sick and is referred to Kilifi which requires money you don't pay anything, everything is paid for. This encouraged some people (to join the study) because after sometime, people liked this organization (KEMRI)...," (Pax5, female, CSA/HH1).

Often participants compared high quality levels of care provided by the KEMRI-WT staff with the perceived lacklustre services at the public health facilities.

"...probably a child is sick at the dispensary, and there is the KEMRI section and that of the government. So on the KEMRI section the child gets quick treatment and the treatment the child gets is that of high quality. They *chunguza* (investigate) the illness and then treat. And in our hospitals they do not investigate; you just tell the doctor how you are feeling and they just assume its malaria, and give you drugs, they do not investigate...," (Pax5 male CSB/FGD08).

For FWs, being part of the community, and aware of participants' contextual challenges, contributed to emphasizing benefits.

"...but you know they are going there (at the dispensary), sometimes the medicines are not there... when they are in the study, they are referred to here (KEMRI), they are subscribed for medicine here... They would have queued for long (at the dispensary)...," (FW4 male, CSA/FGD07).

Staggering study benefits over time in response to participants' (and FWs') requests was highly appreciated and seemed to show that researchers were sensitive and

responsive to participants' needs, and potentially increased participation and retention. Indirect benefits introduced over time such as chairs given to households in case study A, and waiving of user-fees for parents and guardians in case study B, were hugely appreciated by both participants and FWs. However, successful negotiations on benefits also appeared to have created an expectation of more benefits and tokens over time, possibly fuelled by promises made by FWs.

> "...and I think some (participants) remained in the study just because they have some hopes that at the end of the study maybe something will be given. Yea I was told this in another household I visited yesterday that he (participant) doesn't really like to participate but maybe at the end of the study if there is something that will be given then we (FWs) might report that this person didn't participate for quite some time (*all laugh*)..." (FW3, male, CSA/FGD05).

During my field visits at the end of case study A, I noticed that many households requested tokens for having persevered with the study; possibly in response to earlier insinuations from FWs. What benefits to give when, and the possibility of inducement, was a point of contention among the researchers, FWs and CAST members[71]. Some researchers felt strongly that participants who had already consented could not be unduly influenced, and that arguments about undue inducement were sometimes used to reduce or deny participants benefits:

> "...if I were to decide for this study about the benefits to be given, having been at these households, I would have a very long list of cheap things we can give the households and they would appreciate. Although I know it would be like we are inducing them to participate in the study but they are already participating in the study, so I don't think introducing extra benefits at this time would have much effect on their participation. And then the only danger is about rumours that might come out of that, and other studies that are coming in future, but I

[71] For description of CAST, See 3.6.1.

think that should not justify not giving additional benefits" (R2, female, CSA/IDI02).

Some argued that given the wealth of the institution and the high poverty levels in the community, studies could give more benefits to participants and communities.

> "...but that issue (of additional benefits for participants) kept coming up, I think. in practically all of our meetings. We used to feel that, on compensation and benefits, we need to give them something more. And in the long run, each one of us who actually got into contact with those participants or within those households, I think we all felt that we did not give enough... This is a big study, they (participants) have made it succeed, it's them who have made it a success, so we should also be able to give them something tangible" (R2, female, CSA/IDI05).

Some researchers felt that one way to counter undue inducement is to give benefits to whole communities rather than individuals, in consideration of the long-term relationship and willingness of the community to continue participating in KEMRI-WT research. These researchers were also concerned about the implications of growing research costs for future studies. For many studies, the cost of providing increasing community-level and participant-level benefits may be too high. A dilemma, where emphasis is placed on community-level benefits, is that participants might be unwilling to participate.

> "...I believe the idea of balancing (risks and benefits) is trying to ensure that people don't participate in your study just because of the benefits, but again you have to understand people cannot participate in the study if there are no benefits" (R1, male, CSA/IDI01).

One researcher in case study A, who was also a member of the CAST team for the study, had strong views in support of provision of more benefits to participants and the

broader community. The researcher was the link between the FWs and the study PIs. She accompanied FWs to the field almost every day, and in addition, supported the clinical team during home visits. She was particularly frustrated by institutional limitations on what to offer the community, especially when the advice did not seem to reflect realities of household livelihood struggles at a time of drought and famine. The field team estimated that nearly half of the community required some form of food aid over the study period. Case study A researchers requested to provide food items to participating households as part of study compensation for the considerable time taken in follow-up visits. After reviewing the situation, the CAST group declined the request on the grounds that it was not within the overall mandate and focus of the research centre, and because of concerns of intra-community inequity if non-participating households were not also given food rations. Other arguments were: providing food rations in that context might unduly influence participants to join or stay in the study without a good understanding of the research; future larger studies could not provide similar levels of benefits; and other current research in neighbouring areas may face similar demands that cannot be factored into their budgets. The researcher sounded particularly frustrated with being cautioned against providing non-health related benefits.

> "...we have tried to forward this (request for additional benefits) to the CAST team and tried to justify every small thing we give, but every other time we do so in our CAST meeting, we are told again we can't (give benefits). You know, you go there wishing you could be allowed to take a packet of flour to the household and give the household but again our hands are tied" (R2, female, CSA/IDI05).

Referring to the long term relationship between the research centre and the community, she felt that the research centre has a humanitarian responsibility to help communities

where needed and especially in emergency situations, as happened in case study A when a cholera epidemic affected the study population. Describing these dilemmas of what to provide and to whom, she noted:

> "... you can't see cholera affecting the place and you just sit back and yet you can do something about it. And you can't also say now that only 3 of our participants have cholera we are only treating those ones. Then again, if the dispensary lacks paracetamol which is a very basic drug, and we have; we can afford to get paracetamol for them, then it's our social responsibility to them (community)" (R2, female, CSA/IDI05).

How far to extend such humanitarian aid and for how long appeared to this researcher to be irrelevant when faced with emergencies; the researcher's response was that the research centre, and the studies in the area, should try to address these issues. Most researchers seemed to agree that there was a need to be sensitive to and responsive to community needs, even for non-health related issues, and preferred a mix of both community-level and participant-level benefits. The challenges and tensions remained over what to give, whether to restrict this to health related benefits, the appropriate levels of benefits, and mechanisms of delivering them.

8.4 A key coping strategy: social relations between FWs and participants

As hinted at throughout the previous sections, the type of relationship between FWs and participants emerged as a coping strategy for FWs, but also presented new dilemmas. In this section, I first describe how social relations evolved, followed by the associated dilemmas for FWs.

8.4.1 Trajectory of social relations between FWs and research participants

The process of FWs establishing their professional identities and relationships as KEMRI-WT staff at households, and how these intersected with their social lives, informs the nature of research interactions and the types of dilemmas FWs faced.

Establishing and consolidating relationships

Although FWs were already known in the community, as family members, friends, neighbours, and as part of the community, studies followed several steps in introducing FWs to the community to mark the beginning of their professional identity (see 5.3.3). It seems that at initial interactions, FWs were trying to figure out how to balance their professional and social roles and identities. For example, it is taboo for a man to sit close to, or directly opposite, a married woman in the absence of her husband. Taking of temperatures in case study A involved inserting the thermometer under the armpit of the participant which required FWs to seek permission from a woman's husband, and to carry out the procedure in the presence of others. Initial difficulties were overcome through behaving respectfully in households, and allowing time for consultations. Participants appreciated the care with which FWs handled them and their children.

> "...they see that you are very much concerned about the child, so that (good) relationship develops…," (FW10, male, CSB/FGD08).

Over time, familial titles such as daughter, son, grandchild, were used, indicating evolving kinship-like relationship between FWs and participants. As a male FW in CSA remarked, *'...you have become like one of the family members' (FW4)*. Related to these evolving relationships appeared to present familial and friendship responsibilities to FWs, with participants requesting for food items, cell phone airtime and baby

clothes; and FWs wanting to offer assistance to households. The latter was the case even when assistance was not requested.

> "Okay, when a relative to a participant passes away, we go there and console the family, and if there is something small, we give..." (SFW3, male, CSB/FGD11)

Some participants also pleaded to be excused from unpopular study procedures, apparently hoping that FWs, who were almost like family members, would be compassionate and willing to change some study procedures to accommodate their views.

FWs were sometimes also consulted on non-study related issues such as land ownership, planned community development projects and mentoring of young people. Some FWs described feeling happy that they could give back in these ways, it also strengthened their status within households. However, these roles also further blurred the boundaries between professional and relational responsibilities.

Changing FWs and ending studies

Exit of a FW from a household also followed a systematic approach aimed at minimising disruptions. Handing-over to new FWs included new FWs being introduced to households by the old FW, pairing up of the old and new FWs for a period of time, and continued support to new FWs post-handover. The process of handing-over mattered to FWs and researchers because changing FWs and/or exiting from a household was about breaking or changing the nature of relationships that had evolved, and some participants were likely to resist this.

> "So the participants once they are used to one fieldworker any other fieldworker turning up at that home has a difficult time. They fail to trust us at all. And then even the young children some of them shout at you to bring the FW they are familiar with so they can be swabbed. So it's really difficult for a fieldworker to be given another household to cover for another FW..." (R2, female, CSA/IDI02).

While many of the households readily accepted the new FWs, others were reluctant and a few refused. Reasons for reluctance included doubts about the new FWs' competence, and not wanting to break relationships with previous FWs. New FWs reported using various approaches to (re-)establish good relationships including extended visits to households, re-explaining the study, reassuring participants of safety of the study procedures and generally re-building mutual trust and respect.

The exit strategy rolled out for case study A (see 4.3), while important in reducing levels of interactions also appeared to signify a continuity in the relationships established.

> "In fact they miss you so much. The moment they see you even on the road, on your own business, they just request that even though you are through with your study you should find some time to just come and say hi, 'don't forget us as such', they feel you are part of them..." (FW3, male, CSA/FGD07).

8.4.2 Field workers' dilemmas associated with social relations

Overall, trust was a core element in FW-participant relations, with elements of a strong almost 'blind' trust towards the high quality health care, but also some mistrust towards the intentions of the care, and about its' research. Where there was trust and loyalty in the relationships, there were concerns about any indications of the FW being investigated or in trouble, including some concerns about my role in the research

presented here (see 4.7.1).

Positive relationships were recognised as crucial to study success and were built up through intense and frequent interactions between FWs and participants. The related challenges were around relational responsibilities and expenses; potential loss of friends for being associated with KEMRI-WT; silent refusals and study benefit distribution; and of being too familiar and not being taken seriously.

Increased expenses and benefits to low income households versus showing respect

Local social norms require that friends carry small gifts when they visit each other. In some households, FWs were offered meals even when there was clearly not enough for everyone in the household. FWs' sharing a meal was seen as a sign of respect to the household, of being accepted into the family; declining a meal or offering monetary compensation would be seen as being impolite. Sharing a meal however introduced dilemmas for FWs. Should they give something back in return? Who would pay for that? Would acceptance of food lead to families preparing relatively expensive food? Would it undermine the professional status of the FW? Would it take too much time-out of work for FWs and for participants? While there were no clear solutions to these issues, it was generally agreed that FWs could politely decline a meal after assessing the situation the household was in.

Related to this, FWs wanted to increase study benefits, including to other non-participating community members (see 8.3). FWs reported feeling caught between empathising with participants, and wanting to follow the study protocols.

> "...and then again the household expects so much in return (for participation) in terms of the benefits for the study. So a fieldworker goes there and since s/he is

the only person related to the study, sometimes they ask so many medical questions about people being sick and even some of their neighbours" (R2, female, CSA/IDI02).

For FWs, relationships at the end of studies were simply extended, not ending. It is possible that FWs' hints of greater participant benefits described in previous sections created hopes that tokens would indeed be provided. When they did, it feed seemed to feed into strong relationships; when they were not provided, there was a risk of undermining trust.

Building inappropriate levels of trust

Particularly in case study B, participants and community members often referred to FWs as doctors. FWs appeared ambivalent about this: although a sign of respect, they could not handle some of the medical-related issues raised by some participants.

> "... (on being referred to as a doctor) partly you feel stressed and partly you feel like you have been promoted. Stress comes in when someone who is not in the study comes to you when sick, because s/he knows you, s/he believes you are a doctor; so if s/he becomes sick s/he runs to you (*all laughing*)" (FW2, male, CSB.FGD10).

> Initially, we were hesitant about that issue (being called doctors). I almost told a mother that I'm not a doctor, I'm just a field officer. But now you see you will have a difficult time because the confidence she has in you will be lost...so it becomes hard for me to tell her that am not a doctor, because I'll have to give her another name, but the work I do seems to be medical, it also confuses them..." (FW1, male, CSB/FGD10).

Being associated with KEMRI-WT activities versus loss of friends

As described in 5.2.3 , some dilemmas FWs faced were related to being associated with 'devil worship' activities of KEMRI-WT. Being taunted and mocked, and sometimes rejected by friends and own family members was especially stressful for some FWs.

> "...I wasn't feeling well so I went to another kiosk to buy some painkillers...they saw [my work] T-shirt and then one shouted 'you know what? The devil is here, in full swing' (*laughter).* I told him I felt bad then and the rest laughed at me" (FW4, male, CSA/FGD07).

Questioning of FWs' allegiance caused emotional distress for some FWs, sometimes led to loss of friends, and in a few cases led to being rejected by their families. One FWs' mother rejected any form of assistance from him, including food and money, because she believed by accepting employment at KEMRI-WT, he had joined a 'devil worship' cult. She also refused other family members from joining the research.

> "...first I left her (my mother) alone....so it had got to a point that other mothers were asking why is it that fieldworkers are recruiting from other homes and they don't want children from their home to join in the study. This went up to the PI. Even recently, another child (from my home) qualified (to join the study) for 6-12 age-group. But even for that, I didn't even try to talk to her (my mother) about the child...even today, my mum if I take to her maybe money may be its end month and I have received my salary, she cannot take it (FW3, male, CSB/FGD08).

Partial participation: silent refusal

As described in 7.3, one of the factors contributing to silent refusals was safeguarding important relationships and avoiding conflicts. The dilemmas for FWs were whether to drop silent refusals. If they did this, they might later be blamed by participants (who often became more comfortable with procedures over time, and who appreciated study benefits), and by study supervisors (for a reduced sample size). On the other hand,

retaining silent refusals implied continuing to collect low quality data for a while, requiring repeated explanation to PIs. Whichever course of action FWs took, there were likely to be some strained relationships, even if temporary, between the FWs, participants and researchers.

Being too familiar, not taken seriously

A key feature of relations between FWs and participants was mutual respect. While familiarity and informality enabled free discussion, high levels of familiarity could also have led to a perception of lack of seriousness or even disrespect. Disrespect was discerned in the way participants and FWs talked to each other, and in casual interactions or in interactions with sexual undertones.

In FGDs, male FWs reported instances where they perceived inappropriate interactions from female participants. For example, a young woman opened her blouse to a married male FW when he was taking her temperature, and a married woman asked for a loan from a male FW and did not want her husband to know about it. FWs expressed vulnerability in these situations; which could potentially have led to loss of participants, marital conflicts, and a longer-term issue in damaged reputation for themselves or KEMRI-WT. Some FWs informed researchers, some sought advice from fellow FWs, others waited out for the end of the study, and others still informed other household members in an effort to re-establish trust and respect.

Sometimes FWs also found they were caught in pre-existing intra-household tensions. One married male FW narrated his helplessness when embroiled in marital conflicts with an estranged couple living in the same compound. The FWs' frequent visits to the

homestead at out-of-office-hours for follow-up activities, as per study protocol, were perceived by the estranged husband as attempts to seduce his wife. The FW was nearly beaten up during one of the follow-up visits. The husband only allowed the FW to continue following-up the family when he saw other FWs visiting other households at similar times.

> "He (estranged husband) then wondered, you were here in the morning and now you have come back at 6pm, what brought you here? So when I explained to him he said, 'no stand up and go'. He then started holding me, he pulled me and forced me to leave. While he was holding me, his wife came in, he asked her 'what are you doing with him (FW)?'...I had courage, I controlled myself...I then told him that I am leaving because this is your homestead but there are two things that I want to explain to you, that KEMRI is an organization that does different types of research. In our research...staff have to work past 6pm because of the school going children...I cannot follow them while they are at school and that's why I have come now to take the samples. That's the first thing and secondly instead of once I will be coming twice in every week so that's all, I left" (FW1, male, CSA/FGD05).

Related to the above, the caring attitude of FWs towards participants was a source of jealousy among married men (see 7.2.3) who feared that male FWs were taking over their roles of providing health care to their wives and children. FWs found this frustrating, but recognised that being socially embedded in the community carried certain responsibilities including knowing how to respond when faced with such challenges.

> "...there is a way in which you (FW) can be in the community. Because this work has certain challenges, how do you situate yourself in the community, are you respected first of all? and do you respect yourself?...so, anytime a mum comes to you, and asks for help, she can request even for advice, you have to think, what should I do? Because you don't want to cause problems with her husband...," (FW male CSB/IDI07).

At the micro-level, handling different households and different individuals in a household required FWs to be aware of appropriate responses to household dynamics, and sensitivity to issues that mattered to participants. As one FWs said "*we had to know these households, I tell you, what worked in one household did not always work in another, each day was a learning lesson...,*" (FW1, male CSA/FGD05). Challenges that FWs faced might probably sound like the normal daily occurrences in any employment institution. They are however particularly important in regards to FW roles because of the ethical implications for research implementation. I now turn to support systems that were available for FWs in the two case studies, and FWs' views about them.

8.5 Use of supervisory support for FWs

Support to FWs included initial training on the study protocol, in communication skills and information in informed consent forms. On-going support included weekly meetings with immediate supervisors, and with the PI (case study A), and on-the-job training based on areas identified as requiring such support. The level and types of supervisory support for FWs in the two case studies differed. There was more direct daily support for FWs in case study A because their roles were likely to affect the scientific validity of the research more directly, and the study covered a smaller geographic region. In case study B direct supervision in the field was less frequent, and often offered by the community facilitator attached to the study.

8.5.1 Factors influencing use of the support system

Factors influencing the level and use of the support systems that were available to FWs in the two case studies included confidence in the system and the intra-team relations, which I describe.

Confidence in systems

Where FWs were confident that the system will be supportive of them, they were more likely to seek help with a problem. At the initial stages of the study, FWs appeared hesitant to seek help because they were still learning study team dynamics, and how PIs would respond to them. FWs highly praised researchers who appeared to understand their issues and who accompanied them in the field because it provided opportunities to know the researchers, for the researchers to appreciate the issues that FWs faced and to take those issues seriously.

For example, at the onset of case study A, FWs' complaints of increased workload and challenges in collecting samples were seen by some researchers as excuses for underperformance. This led to a silent revolt by FWs in which they decided not to work at weekends until their terms of employment, including monetary compensation for extra time worked (instead of the official leave days in lieu), were reviewed.

> "Like there is that meeting that we had where we...just kept quiet. When I asked my colleagues, the response was like 'there is no need for you to waste your time and energy trying to explain something and then get nothing out of your explanation ...there is nothing that is going to be taken seriously. So we just decided to keep quiet and take things the way they are," (FW5, male, CSA/FGD05).

In time, senior researchers joined the FWs for field visits, assisted them in handling difficult participants, identified areas for further on-the-job training, and began to allow some flexibility in study procedures, such as partial participation. Having researchers accompany FWs in the field greatly motivated them, as it led to researchers actively seeking FW views and acting on them.

Intra team relations

Approachability of researchers and FW supervisors appeared to influence FWs' use of the support systems. Where FWs felt undermined or where they had strained relations with their seniors, they were less likely to discuss issues they faced in the field. Early study team meetings were largely driven by the researchers and were aimed at ensuring FWs had appropriate skills to carryout study procedures and respond to questions. FWs felt undermined when issues of their welfare and workload were overlooked.

> "...it's like those guys (PI and researchers), we will call them bosses; they already come with their fixed ideas and decisions such that whatever we say it's not going to be heard (listened to); it's like we have to follow what they have come with...," (FW3, male, CSA/FGD05).

A subtle reminder by one researcher in case study A to FWs that they had not passed their probation period was viewed as a form of intimidation to meet study targets. Intra-team tensions also arose from perceived biasness of supervisors to staff. Unfairness was perceived where individual FWs were given different resource support and responsibilities. Delays in addressing issues raised by FWs influenced the extent to which they used the support system. Timely communication of study progress, being informed of flexibility in study procedures and of FWs working conditions were seen as effective ways to support FWs.

"...on the other hand, the PI and the coordinator, listening to what we used to tell them about fieldwork, and understanding what we meant and seeing for themselves by associating with us (FWs) in the field... contributed a great deal (to success of the study)", (FW3, male, CSA/FGD06).

FWs appreciated individual feedback on their performance. They felt respected and valued, not undermined as happened where individual underperformance was discussed in team meetings (see below). However, where researchers hardly went to the field, and where SFW were largely based in offices (as happened in case study B), FWs felt less supported, and reported using peer support systems more often. Monitoring systems to countercheck data quality such as spot checks and multiple data entry points were viewed by some FWs as veiled distrust in their honesty.

8.5.2 Performance monitoring as FW support?

Both case studies had multiple crosschecks including:

- For case study A, weekly random testing of some samples, and of consistency on information filled in various forms; a master log[72], log-in sheets for samples delivered at the main laboratories in Kilifi and a weekly summary sheet all samples.
- For case study B, counterchecking of clinical visit information with that of Passive Case Detection (PCD) reports, and FWs reported number of recruited participants.

Few incidents were reported of data falsification. FWs in both case studies said that falsifying data would have been difficult because of the rigorous quality checks in place, as one FW in case study B said,

[72] A hard cover book filled by each FW for every sample collected at the end of each day. FWs used to fill the master-log information in turns.

"...if you fail (to do follow-ups) and the child falls sick and you have the diary here, what will you say (to supervisor)? Maybe the child has been treated here (dispensary) and the temperature taken was 39^0C, and you fill (in the diary) 36^0C... you will be discovered...," (FW3, male, CSB/FGD09).

Commenting on data falsification, researchers and FW supervisors observed few cases of data breach. Their concerns were whether FWs gave accurate information to participants, because this was difficult to monitor. Researchers felt that the data quality checks were helpful in detecting potential data falsehoods, identifying challenges FWs faced and the type of support they required.

Views on FWs performance monitoring

Information on weekly samples collected by each FW were summarized into a performance chart (see Appendix N) introduced mid-way through the study in case study A. Weekly FW performance were compared against each other and against a minimum level and maximum target. As one researcher said, the performance chart was to *"...track each fieldworker and assess whether they are doing their work in terms of volume"* (R, CSA). Researchers viewed the performance chart positively, in helping to identify the type of support required by individual FWs, and in building a sense of collective 'ownership' of the study.

"...so I think it (performance chart) caused them to work harder than usual because initially you could see specific people had less number of samples, so it made us (researchers) ask them why. Of course most of the fieldworkers were initially not reporting difficult cases (participants), they then started reporting them because... these dragged them down (lowered performance)... it made us to change a few things. We noticed the senior fieldworker could not follow all his participants because he had a lot of work..." (R2, female, CSA/IDI05).

Researchers were aware that the performance chart was raising concerns among the FWs that performance was being judged.

> "...and yet a refusal is a refusal; it's not about you the field worker, but it's really about the participant. So it (performance chart) caused them to feel like we were biased against some of the fieldworkers, but we were not..." (R2, female, CSA/IDI05).

FWs appeared generally ambivalent about the performance chart; some felt that it motivated them to work harder and to find ways to handle difficult participants. Other FWs felt that the performance charts were a form of pressure from researchers to meet targets.

> "...come Thursday (meeting day) the PI used to sit there and ask the same question 'ah (FW4) tell me did you sample that household? ...and you know there were those graphs (performance chart), that will be distributed here; everybody has his graphs. And some, they click (get) 98, 99, yours is 50 (per cent), and because there is a refusal they (researchers) said 'I don't want to know if there is a refusal, at the end of the day samples have to be here'..." (FW4, male, CBA/FGD07).

Some FWs also blamed the introduction of the performance chart for causing unhealthy competition amongst them leading to claims of sample pilferage.

> "I feel that the performance chart is good...because on Thursdays, every fieldworker is given his paper (chart) showing how he/she performed. ...you may ask (another FW) [to assist you]...but on the other side it has its advantages like sometimes you'll go to the field collect samples you come here it's late you store the samples on the freezer you go home ...and when you come in the morning, the sample is gone [stolen]...," (FW4, male, CBA/FGD07).

The SFW, the study coordinator and other FWs felt that the samples were not pilfered but were most likely misplaced in the freezer; they could, however, not explain why they were never found. The worries for the FWs affected was that, in addition to affecting his/her performance, he/she had to figure out how to explain to the participants that their samples were missing.

> "...imagine you find your sample are missing. Mind you, you cannot go back there to the same person to get more samples because it's not allowed professionally. So all those (problems) are brought by that document (performance chart), a *very good bad document* (all laugh) [italics my emphasis], (FW2, male, CSA/FGD07)".

The seriousness with which the FWs took the performance chart was illustrated by an incident narrated in all FW FGDs in case study A. A three-day delay in replacing the master log book made some FWs work day and night[73] to ensure their samples were logged in time for the next day's team meeting. FWs who consistently performed well expected that they will be rewarded in some ways, by extending or renewing their contract.

> "...because you know it's like human nature that when you are given an activity or a job, and you perform very well, you expect that another time when someone gets a similar job, they will look for you first, as you can do that job..." (FW4, male, CSA/FGD06).

There were clearly different views between researchers and FWs, and within the FW team on the purpose of the performance chart, requiring sensitivity on how such a tool is introduced and used in a study team.

[73] All FWs had to fill in the master-log, which could only be filled by on FW at a time.

8.6 Chapter conclusion

This chapter described the various coping strategies FWs used to resolve challenges they faced in the two case studies. Some of the strategies were around reassuring participants and addressing participants' concerns and fears. Continuous consenting, counterchecking of study-related decisions and discussions with participants were key to all study-related interactions. The central role for FWs in the studies, carrying out follow-up activities and delivering some of the study benefits, appeared to place them in positions of power, to negotiate how research happened with participants and with researchers. In these negotiations, there appeared to be a thin boundary between information-sharing and persuading participants to remain in the studies, with study benefits being central in those negotiations. As well as being compensation for study participation, benefits were discussed, and understood, as gifts or rewards for consistent participation; withdrawing of study benefits to those who dropped out of research was sometimes seen as a form of sanction.

Inevitably, social relations between FWs and research participants were an important medium in which study and social activities took place. It was facilitative of ethical research though enabling FWs and participants to know one another and discuss issues that mattered to them; and address these in mutually acceptable ways. Familiarity between FWs and participants appeared to contribute to better understanding and acceptability of the study, and transcended boundaries of study procedures and processes to build and consolidate positive social relations. Familiarity also presented dilemmas for FWs, on how to balance professional requirements and friendship responsibilities. This was important because FWs needed to be objective in undertaking some of their roles, but also required them to be sensitive and responsive to participants' situations. A fine balance between the two, encouraging mutually

beneficial relationships, was said to contribute to the success of the two studies, in participant retention and collection of data. The social relations were described as important in making the studies happen. FWs, being in the middle of these relationships, required appropriate support to implement the research ethically.

Several support systems were available for FWs in both case studies. It was expected that FWs would use these when needed. It was also anticipated that FWs would solve some of the challenges they faced themselves, which strengthened the need for foundational training they received at the start of each study, and the continuous supportive supervision throughout the study. It seemed that the extent to which FWs used the support systems depended on several factors, some of which were about how well the system worked, and appeared to relate to intra-team relations. While supportive supervision was generally well received by FWs, it also appeared to depend on whether FWs felt integrated enough in the study team, and whether they felt they were treated fairly with respect and dignity, and that their issues were taken seriously.

While support systems could help redress or provide deeper understanding of the challenges FWs faced, there were no easy answers. Some of the challenges seemed to create further dilemmas, the dimensions of which could only be understood under the context they happened; in the field, with a particular group of participants, in a particular set of relationships and at a particular time. Some of challenges presented as practical issues, might even go under the radar of what might be termed as an ethical challenge. For example, should a FW accept a meal when they visit a household, or lend money to a married woman? Some of these appeared to present tensions between local norms and ethical guidelines, for example, whose decision to accept when a

minor's dissent contradicted the consent of all adults in a household? Might respecting the minor's dissent cause rifts in the household? These issues illustrate the ever-shifting dilemmas FWs encounter, the need for on-the-ground responsive support to FWs, and moderation in making quick judgements of FWs' conduct as 'unethical' or 'exploitative'. It further emphasises the need for practice-based training for FWs and strengthening their skills in weighing-up consequences of options and choices when faced with challenges. Beyond the micro-level, these issues emphasis the open ended, never ending ethical challenge of inequality that underlies this work, and the reason to continuously worry and keep reflecting on how well the ethical guidelines work in practice.

This chapter marks the end of the empirical finding of this research. The next chapter, which is the last chapter in this thesis, brings together four cross-cutting issues that emerged from the empirical chapters: issues around consent process and messy realities for FWs, the centrality of study benefits in research negotiation, power and vulnerability in research conducts and finally the interface role of FWs in all these areas. I discuss these in relation to the literature.

CHAPTER 9 Discussion and Recommendations

9.1 Introduction

The last three chapters presented the empirical findings of this thesis. In this final chapter of the thesis, I discuss four main issues emerging from the empirical work, with reference to relevant literature. In so doing, I address objectives 5 and 6 of the research: Objective 5: *To explore the implications of fieldworker and research participant interactions for research implementation and ethical practice,* and Objective 6*: To develop recommendations for supportive supervision of fieldworkers in this and other similar settings.*

The chapter is divided into five sections. I first revisit the research gap identified from the literature review and summarize the main findings of the empirical chapters (9.2). I then discuss four inter-related issues emerging from the empirical findings (9.3), and revisit the forms and extent of generalisability of this research, before making some recommendations (9.4). In the last section, I discuss areas that require further research (9.5).

9.2 Summary of the key findings

This social science descriptive study aimed to contribute to discourses around the practical and ethical challenges of involving community members (FWs) in research activities. Through experiences of fieldworkers employed in a long-standing research programme, KEMRI-WT, the research explored the nature of research-related

interactions between FWs and research participants generally, and in two community-based studies.

Six objectives were identified and each of these investigated. Table 9.1 presents the six objectives, a summary of the key findings under each objective, and the empirical chapters the findings relate to.

Table 9.1: The research objectives and summary of key findings

Specific objectives	Main findings
Objective 1: Develop an overview of who the fieldworkers are in KEMRI-WT, including their roles, overall expectations and concerns with their position in the institution. Chapter 5	• FWs (n=243, 157 male and 86 female) are the largest group of staff at the research centre, forming nearly a third of the total staff. • Employment and career progression appeared skewed in favour of male FWs. • Formal FWs roles included undertaking consent, following-up of participants, and carrying out 'simple' non-invasive study procedures. It also appeared that FWs were doing a whole lot of community engagement activities. • Employment of FWs was highly appreciated, but there were also concerns related to geographical distribution among the KHDSS community. • FWs reported ambivalence towards employment at KEMRI-WT, related to good reputation of high quality health care provision and good salaries, but also due to negative rumours about KEMRI-WT's work. • They were also dissatisfied with unclear policies in regards to promotion and career progression pathways.
Objective 2: Describe two key areas framing the interactions between FWs and participants in the case studies: household decision-making norms around research participation; and participants' hopes and anxieties. Chapter 6	• Participants' hopes, fears, and anxieties were underpinned by previous and current experiences with KEMRI-WT activities, perceptions and reputation of the research centre, and study information provided. • Fears and anxieties shaped nature of interactions with FWs, manifested either as non-conformity with research protocols or as persistent enquiries that took much of FWs' time. • FWs faced complex household decision-making dynamics • Research decisions were negotiated across these household dynamics with important factors considered including gender roles, intra-household relations, perceptions of risks and responsibility for research participation • A particular challenge for FWs was in handling discordant decisions at household, because of potential to cause further differences. Discordant decisions illustrated circumventing of unfavourable decisions by some household members who are not involved in the decision-making process, or whose decisions are

	not always considered. FWs needed to be aware of these issues to know how to respond to them.
Objective 3(a): Describe the main challenges faced by FWs in their interactions with community members. Chapter 7	• Challenges FWs faced included those about their technical competence (information, communication skills and competence in carrying out follow-up activities), and those about handling different household members. • Silent refusal emerged as particularly problematic for FWs due to multiple factors associated with it, including study benefits distribution, safeguarding important relationships (including those with the FW), and preserving harmony at the household. • A further challenge associated with silent refusal post-consent were data quality concerns due to inconsistent participation.
Objective 3b: if and how challenges were resolved *Objective 4*: Describe emerging dilemmas for FWs in their interactions with participants, including those associated with silent refusals, levels of benefits and the development of social relations. Chapter 8.	• While various strategies were used by FWs to address challenges they faced, it emerged that two interrelated strategies (study benefits and social relationship) appeared to have major practical and ethical implications on FW roles and research conduct.. • Study benefits were central to study negotiations, used to consolidate relationships, or sanction research participation; information in consent forms was used to further validate the actions that FWs took. • Relationships between FWs and participants were dynamic and evolving over time. Associated challenges and dilemmas for FWs included miring of boundaries between professional and friendship 'faces' of FWs. • In both case studies, study benefits and relationships between participants and FWs were said to contribute to the huge success of the studies in participant retention. • Various support systems were available to FWs in both case studies, however their use by FWs appeared to depend on several factors including perceptions of their effectiveness, fairness and competence of FWs to use them.

9.3 Key emerging issues

Emerging from this research are four key issues with implications for the practice of ethical conduct of research in community-based studies. In this section, I discuss these issues with reference to the relevant literature, and thereby address objective 5 of the research. I grouped the four key interrelated issues into two sections. The first discusses two core topics in the empirical findings:

- consent processes and study retention: messy realities and the central role for FWs; and
- the centrality of research benefits and relationships in research negotiations;

The second section discusses two main issues emerging from the empirical chapters and that cross-cut the above two issues:

- power and vulnerabilities in research conduct; and
- FWs as moral agents doing ethics;

9.3.1 Consent processes and study retention: messy realities for FWs

Awareness of challenges of gaining 'truly informed' consent for research in developing countries (Chapter 2) contributed to the design of the consent forms and the additional measures put forward to support consent processes in the two case studies examined in this research. Even then, challenges were experienced at both consent-seeking stages of the studies, and at study retention. I discuss these challenges in turn, the way they were resolved and the implications for the research conduct.

Challenges FWs faced with initial consent

The main challenges FWs faced at initial consent were related to terminologies, low study acceptability, participants' understanding, and decision-making dynamics within households. These challenges are typical problems in these environments and are widely documented (Lema, Mbondo et al. 2009; Mystakidou, Panagiotou et al. 2009).

With regards to terminologies, participants tended to link terms with study risks and adverse events, showing some elements of crowding-out of information given through prioritizing information that was more interesting and which they were most concerned about, as we have previously described (Marsh, Kamuya et al. 2011). In addition, fears and concerns (and resultant low study acceptability) appeared to mask bigger and

deeper concerns with KEMRI-WT's work articulated through rumours about its work, which were weighed-up as part of risks for being involved in KEMRI-WT research.

Rumours with regards to research have been documented in similar settings (see for example Mitchell, Nakamanya et al. 2002; Geissler 2005; Fairhead, Leach et al. 2006; Geissler and Pool 2006). They are likely to be related to a range of factors including: wealth inequities, historical injustices (Geissler and Pool 2006; Graboyes 2010); unclear understanding of research and sources of research funds; symbolic representation (such as snake logo); and unpleasant outcomes such as death in health facilities in which research is being conducted (Molyneux, Peshu et al. 2005; Geissler and Pool 2006; Kingori, Muchimba et al. 2010). Many authors argue that rumours need to be taken seriously because of the potential to mask deeper concerns in the community (White 2000; Geissler 2005).

Whether FWs' strategies to handling concerns led to participants understanding research is complex to measure (Krosin, Klitzman et al. 2006; Molyneux, Gikonyo et al. 2007) and was not an aim of this study. There were some suggestions that many participants did understand elements universally considered as key to consent processes such as purpose of study, procedures, risks, and benefits (Bhutta 2004; Williams, Irvine et al. 2007). That a good number of potential participants declined enrolment to the study suggested that many were aware of their ability to refuse and exercised that choice (Lavery, Grady et al. 2007 p280). Where there was an apparent understanding by participants, this was attributed to continuous dialogue and discussions during follow-up periods for the studies. However, a level of therapeutic misconceptions also appeared to exist for some of the participants (Appelbaum, Roth et al. 1982; Appelbaum, Lidz et al. 2004; Molyneux, Peshu et al. 2005). Interestingly in case study

B, there appeared an overwhelmingly positive expectation of the success of the research, because potential for positive results was emphasized by the research team (especially FWs) as the study was at pre-licensure stage, and due to participants' belief that those in the study were less sick less often

Another area that was of great concern to FWs (and PIs) was *how individual decisions and choices might affect household dynamics* (see 6.3). Households were extremely diverse, requiring FWs to be aware of and respond to this diversity in research decision-making processes. Normative gender roles, perceptions of levels of study risks, association with the wider research centre, previous illness experiences, and perceptions of the work of the research centre were some of the factors that appeared to influence research decisions. As can be noted, decision-making was not simply about individual choices, but also the implication of those choices for intra-household and intra-community relations.

The importance of household decision-making dynamics in health care and in research in this setting have been described (Molyneux, Murira et al. 2002; Molyneux, Peshu et al. 2005). With regards to initial research decisions, I found a complex process of consultations within the household and with other social networks - including with participants and FWs - for individuals and for the entire household. This could be because the two case studies involved well people and were based in the community with most of the follow-up happening at participants' homes. It also shows that the process of making research decisions was a relational activity, and that the extent to which individual autonomy was respected was not easily ascertained. A recent descriptive cross-sectional study in Southwest Nigeria similarly showed that decision-making for research is a relational activity involving consultations with others for the

majority of participants (spouses, friends, families) (Osamor and Kass 2012). It also showed that more women than men sought permission from their spouses, and that the majority of participants would have participated in the study even if those they consulted objected (Osamor and Kass 2012).

With regards to who made the final decision about participation, in my study, it seemed that on face-value, male household heads were often the preferred authorities. As documented elsewhere for treatment seeking there are general norms within households, which give power to elders and males in decision-making, particularly where decisions involve children (Molyneux, Murira et al. 2002). My research supports the claim that these powers need to be taken seriously; it was clear from my interviews and observations that there could be major consequences for married mothers in making independent decisions without consulting with or getting permission from their husbands and elders (see 6.3.3). On the other hand, these powers differ markedly between households, are difficult to predict and not always explained up front to fieldworkers. These power relations and their complexity are described in detail in 9.3.3.

The severity of potential negative consequences and lack of clarity from some households on what is expected posed an emotional and time burden on FWs at the outset of studies. This was particularly faced upfront for case study A, which required the entire adult population to consent. FWs sometimes had to take a more proactive role than would be expected in negotiating tensions between research requirements and household norms. Attaining collective household decisions in ways that did not cause conflicts or show disrespect to household authority figures was a major challenge, especially where it appeared that there were issues other than those related to the study

that were influencing decision making (for example pre-existing arguments between spouses or adult siblings). The extent to which FWs ensured individual decisions were respected, or at least appeared to be respected, required far more than a mechanistic following of study SOPs; it required FWs to delicately sensitize households on why individual decisions are important in research. As noted briefly elsewhere for social science research (Molyneux, Goudge et al. 2009), FWs responding to and becoming involved in relationships can mean they become embroiled in families' social lives and networks, with both positive and negative potential outcomes, such as encouraging confidence in FWs, and difficulty in keeping a clear and consistent line on benefits (discussed more in 9.3.2).

A more specific household dynamic challenge for case study A was *assent for minors*. It has been noted elsewhere that time and sample pressures can make researchers downplay the importance of obtaining assent from the child once parental consent is secured (Coyne 2010). In many developing countries, where children are taught to respect authority, children may be accustomed to obeying adults and may assent in order to please elders (Coyne 2010). This appeared to happen in case study A, both to preserve household relations and maintain household participation. A potential consequence of this strategy might have been minors continuing to dodge follow-up research activities, as described in 7.3.1. The primary response by the team to assent challenges was to increase minor study benefits such as ensuring there were sweets for participating children. A consequence of this strategy might have been growing demands for benefits as discussed more below.

Study retention and the centrality of relationships

The high retention rates of participants in both case studies, with nearly 94% (47 out of 50 households) in case study A and 83% (748 out of 904 participants) in case study B, was attributed, in part, to responsiveness of the research team to field issues, having a dedicated FW team and support from the research centre. In both case studies, positive relationships between FWs and participants were said to contribute to the success of the studies, supporting similar views elsewhere (Geissler, Kelly et al. 2008; Simon and Mosavel 2010).

The nature of relationships between FWs and participants generally appeared to be positive, bordering on friendships and sometimes kinship. It seemed that relational notions of mutual respect, trust, and reciprocity were common in the two case studies and underpinned research negotiations. In general, discussions between participants and fieldworkers were more focused on study procedures at the earlier stages of building relationships and became increasingly focused on non-study related issues once relationships were consolidated. The dilemmas that fieldworkers faced were also shaped over time: for example the challenge of 'being associated with KEMRI leading to loss of friends' tended to occur in the community entry stage, whereas the challenge of 'being too familiar and not being taken seriously' was more likely to occur towards the end of study relations.

In terms of continued participation specifically, negotiations took on a more relational-based approach over time. Familiarity between FWs and participants attributed to local residency of FWs, frequent interaction at home-based follow-up visits, and the caring attitude of FWs seemed to contribute to study retention, but also presented some dilemmas. Relatedness responsibilities such as sharing of meals appeared to strengthen

positive relationships between FWs and participants, as has been reported elsewhere (Geissler, Kelly et al. 2008; Molyneux and Geissler 2008; Simon and Mosavel 2010).

A particular challenge for FWs at both consent processes and carrying out study follow-ups was handling of silent refusals (see 7.3). Silent refusals seemed to be a negotiation strategy used by participants to choose how to participate in research while continuing to access all the study benefits (9.3.2). I discuss the subtle power explicated in silent refusals in 9.3.3. Silent refusals also emphasises the importance of the ethical notion of informed consent, where participants' decisions and concerns are discussed and revisited throughout the research conduct, and where consent is seen as shared decision making between participants and researchers (Lindegger and Richter 2000). The ethical spirit of shared decision-making appears to be followed through FWs spending considerable time to understand concerns of silent refusals and how they could be addressed. However, this could also have been seen as pressure by FWs for participants to stay in the research, a form of vertical exploitation by FWs (Landy and Sharp 2010).

These points support the centrality of relational ethics in research participation in community-based studies. Relational ethics recognizes the social embeddedness of individuals in their communities and the influence of important social relationships on the self (Christman 2004; Moser, Houtepen et al. 2010). As discussed in 2.4, relational ethics has received significant attention in health care, especially in the nursing profession (Bergum and Dossetor 2005), in medical decision-making for competent adults with chronic illnesses (Ho 2008) and in feminist literature (Mackenzie cited in Christman 2004). However, there is little empirical research on decision-making processes for biomedical research in traditionally communitarian and family-oriented

societies (Geissler, Kelly et al. 2008; Osamor and Kass 2012). This thesis showed that it was essential that FWs took into account important relationships around individual participants for the research to happen, and for FWs to be able to come back and be received positively in participants' homes, and in the community, repeatedly over time. Some strategies that FWs used, such as encouraging research-related discussions within households, could be said to be supportive of good positive relations, and could have strengthened ethical practice. Other strategies appeared to undermine good ethical practice, such as failing to countercheck a father's decision with regards to a child's participation in research when the study SOPs required it.

Another aspect of relational ethics is trust. Contrary to other studies that show an initial almost 'naive' trust in research and researchers (de Melo-Martin and Ho 2008), initial responses to the case studies and to FWs appeared to be fraught with mistrust associated with rumours surrounding KEMRI-WT activities. Over time, trust appeared to have been built, at least in part, by the positive experiences of the study, consistent information given over time and providing study benefits as promised. Particularly important in both case studies is that there appeared to be no serious adverse event (such as death) by the time of writing this thesis. It appears therefore that FWs and researchers were building trust in the research through strategies used to recruit and retain participants, including CE activities for the study.

All of these findings on the consent process and study retention strategies support both the importance but complexity of having fieldworkers implement research in these settings. FWs are best placed to handle some questions in ways that participants easily relate with, on the basis of where they come from and their awareness of the socio-

cultural background of the potential participants (Fitzgerald, Marotte et al. 2002). However, they might have some shortcomings in technical information competences such as understanding the biological bases for studies (Krosin, Klitzman et al. 2006), and are likely to be part of the important social circles of the participants. The way they handle dilemmas associated with their positions can be facilitative or undermining of ethical conduct of the research, illustrating the importance of appropriate supportive supervision systems, discussed under recommendations (9.4).

9.3.2 Benefits: central to research participation and relationships with participants

There is significant debate in literature around the role of study benefits and tokens in research, particularly in developing country contexts (Davis, Broome et al. 2002; Schuklenk 2010; Wong and Bernstein 2011). These discussions and institutional processes and experiences (Molyneux, Mulupi et al. 2012) were drawn on to inform on type, levels and modes of benefit provision in each of the two case studies, with contentious areas revisited during the course of the studies.

Health care benefits featured strongly in discussions and were greatly appreciated by participants; they were the most widely reported reason for households and individuals joining the studies, as also reported elsewhere (Molyneux, Peshu et al. 2004; Kass, Hyder et al. 2007; Molyneux, Hutchison et al. 2007; Leach, Fairhead et al. 2008; Mfutso-Bengo, Ndebele et al. 2008; Tindana, Rozmovits et al. 2011). This is understandable given that many households are quite far from public health care facilities, and that many of these facilities are understaffed, face drug stock-outs, and impose charges (Chuma, Gilson et al. 2007; Chuma, Okungu et al. 2010). Therefore

what might appear to be relatively small benefits for facilities or households (Case study A), or indeed large ones (Case study B) can potentially have a significant positive impact on households such as better care, reduced costs and more accessible health care services. Non-health related study benefits, such as education materials, and sweets to children in case study A, also apparently contributed significantly to retention of participants in both case studies (see 8.3).

Within this positive picture, provision of study benefits appeared to present significant dilemmas for researchers, FWs and participants, in relation to levels and types of benefits, who receives the benefits, and who makes decisions on what these benefits are. What became clearer over the course of studies, and particularly for case study A, was that both participants and FWs were negotiating for benefits against (perceived) risks and contributions from participants. Several points are worth noting in these negotiations. Firstly, risks perceived and felt by participants differed from the physiological risk researchers described in the protocol and in interviews (see 7.2.1). Secondly, benefits of participation were often exaggerated by participants and FWs. Thirdly, as reported elsewhere (Geissler and Pool 2006) the wealth disparity of the research centre in relation to the community appeared to raise hopes and expectations of increased benefits for participants and those working closest to them.

FWs often wished participants would be given more benefits. While FWs were delighted when their requests increase benefits for participants were accepted, they were also aware of resultant intra-household and intra-community jealousies. Sometimes these tensions worked in their favour, particularly where some 'difficult' households later regretted refusing or dropping out of the study (7.3.2). This strengthened, at least temporarily, participants and FW status vis-a-vis non-participants.

Another challenge was how to sustain (health care) benefits for participants and communities, particularly in the absence of the study. Case study B, and similar past studies (Gikonyo, Bejon et al. 2008), showed that there were some elements of taunting and mocking of participants by non-participants when the studies (and benefits) ended.

Recognition of the above challenges contributed to CAST members' efforts to control levels of benefits in ways that did not cause stark inequalities between participants and non-participants. It also emerged that, particularly for case study A (where I had greater opportunities to observe CAST group discussions and reactions from FWs), CAST group members were felt to be unappreciative, in some cases, of the levels of poverty and associated problems experienced by households, and how emotionally draining these were for FWs (8.3). Set against the wealth of the organisation, FWs often felt that responses by the CAST group where these were unfavourable – such as, not to feed households – were unfair for households. On the other hand, CAST group members were concerned about where to draw lines in such low-income contexts, and about perverse outcomes (such as intra- and inter- community jealousies), whether benefits could be sustained and whether precedents would be set for future studies that would be difficult to meet.

These very local level debates echo elements of international benefit sharing and ancillary care debates (Hyder and Merritt 2009; Lavery, Bandewar et al. 2010), and of recent deliberative processes at the research centre (Molyneux, Mulupi et al. 2012). On the one hand, some argue that research and research participation should be based on goodwill and partnership, and aimed at avoiding costs to participants and a commercial relationship (Chambers 2001; Grant and Sugarman 2004; Ballantyne 2008). On the other hand, others argue that research should maximise participants' benefits given the

relative wealth of the research institutions and the multiple community needs (Grady 2001; Lemmens and Elliott 2001; Lavery, Bandewar et al. 2010; Phillips 2012). The big issue for researchers is the extent to which it would be their responsibility to address background conditions of inequity; while some view no responsibility (see for example Wertheimer and Miller 2008), others see some role for researchers (Participants 2004; Lavery, Bandewar et al. 2010)

A central dilemma in amount and form of research benefits is the notion of undue inducement. In the literature, this notion, and the paradoxical relationship with exploitation, has received particular attention in benefits debates. As Koen *et al.* argue, inducement by itself can be ethically justifiable, even if it contributes to participants doing something that they might otherwise not have done (Koen, Slack et al. 2008). Indeed benefits in many studies are designed to encourage participation. However, as noted by Koen *et al*, inducement becomes 'undue' where an excessive offer distorts decision-making, leading to individuals participating against their better judgment. The dilemma, raised by Macklin (1989) and summarized by Ballantyne is:

> '*...offer participants too little and they are exploited, offer them too much and their participation may be unduly induced*' (Macklin 1989 p.179).

An emerging middle position at the KEMRI-WT programme level is to continue to focus on strengthening collateral or indirect *medical* benefits to communities through collaborations with the Ministry of Health to support sustainability. This compromise, it is hoped, minimises risks of undue inducement for individual participants, protects community harmony, avoids a commercial relationship with participants, and protects and strengthens a key relationship with the MOH. This approach might be considered one way to tackle micro-level justice issues (Lavery, Bandewar et al. 2010) in a way

that recognises macro-level justice concerns; for example historical grievances and global inequities that perpetuate poverty and ill health. However, it is recognized that this could only ever be one of a set of approaches to benefit-sharing at both the micro and macro levels (Koen, Slack et al. 2008; Lairumbi, Michael et al. 2011; Molyneux, Mulupi et al. 2012).

This middle ground appeared to be largely appreciated by all parties for these case studies, but a remaining challenge was where FWs encountered the 'non-medical' crisis apparently faced by nearly half of households in case study A, where there was inadequate food for families, and where FWs were not "allowed" under their protocol or the CAST group to formally assist with providing food or cash. They responded in a personal level through, for example, offering personal assistance to community members in need of aid. This strengthened the research because they were seen as caring, or potentially undermined it because some participants might have found it difficult to refuse FWs requests having already received social support. Of interest in this study is the challenging and challenged position of CAST groups in the programme in interfacing between micro-level study specific issues and programme-level guidance.

9.3.3 Power and vulnerabilities in research conduct

Throughout the previous two sections, complex power relations at multiple levels have been alluded to. In this section I explore these power relations in more detail, at several different levels or key points of interaction in the research process: within households, between FW and households, between FWs and their supervisors and the institution, and between communities and researchers. Power in research conduct has received relatively little specific attention in empirical work. In order to assist in unpacking

power in the conduct of research as it emerged from my study, I first present several typologies of power and critiques of these, which I then draw upon in the rest of this section.

The concept of power is highly contested with a common notion being that of *power over* others, thus "A has power over B to the extent that he can get B to do something that B would otherwise not do" (Dahl cited in Lukes 2005 p16). Lukes (2005) introductory chapter summarizes and critiques three conceptual frameworks for empirically investigating power (Lukes 2005). I summarize the main elements of these frameworks, and later I draw on these to discuss the main points in this section.

The first framework of power draws on the work of Dahl et al, in which it is proposed that power can be investigated by studying decision making around key policy issues where there are conflicts of interest or preferences among actors. It makes a claim that those whose preferences prevail in decision-making processes have power over the others. The framework is critiqued for narrowly focusing on decision-making as an observable action, and for the assumption that preferences will be expressed. Bachrach and Baratz's framework (1970) builds on these critiques and proposes, additionally, investigating non-decision making areas. They present various control mechanisms that are used to ensure compliance in both decision-making (as overt observable action) and in non-decision making (as covert unobservable action). The control mechanisms include coercion, influence, authority, force and manipulation, which is a subset of force. Areas outside decision-making are considered forms of power because people's demands can be suppressed, kept covert or otherwise undermined before they can be expressed. Decisions are defined as choosing between alternative modes of actions.

Thus, this framework presents power in both decision and non-decision making, and in controlling agendas that get into political discourses.

The third framework builds on the main critiques of the first (Dahl's) and the second (Bacharach and Baratz's) frameworks and their use of behavioural approaches to investigate power. Firstly, the presentation of decision as 'consciously and intentionally' selected choice out of alternatives courses of action fails to recognize that decisions can be made unconsciously. For example, people may be used to a certain status quo so they do not question it, or do not see other options. Secondly, associating power with actual observable conflict of interest fails to recognize the non-observable influences of power used in shaping and determining people's wants and preferences through thought control and manipulation, which is described as the most supreme and insidious use of power. The third critique is that absence of grievances does not mean there is consensus; rather that power could be exercised in ways that block grievances from being aired. Based on these critiques, Lukes' framework for power incorporates decision and non-decision making actions as well as control over political agendas (not necessarily through decision-making), covert and overt influences, observable (covert and overt) and latent conflicts, and real and intended interests. Illustratively, Lukes makes a claim that "...indeed, power is at its most effective when least observable" (Lukes 2005 p1).

Some aspects of these views on power resonate with themes that emerged in my study. Firstly, a focus on decision-making resonates with my observations on negotiations around research participation within households and between participants and FWs, described in the empirical chapters of this thesis and in the two key issues discussed above (9.3.1 and 9.3.2). Secondly, the description of different forms of power (covert

and overt) is reflected in notions of power alluded to in this thesis and in some aspects of strategies which were used to negotiation for research participation across different key points of interactions. Finally, the various dimensions of power, to some extent, appear to address both macro and meso-level systems approach to power and the micro-level practices of power; both of which are relevant to this research.

With regards to micro-practices of power, I also draw on aspects of it as described in a recent study by Lehman and Gilson (2012) which investigated these with regards to implementation of a Community Health Workers policy in South African. VeneKlasen and Miller (2002), cited in Lehman and Gilson (2012), described power as:

> "...both dynamic and multi-dimensional, changing according to context, circumstances and interests. Its expressions can range from domination and resistance to collaboration and transformation" (p3).

Table 9.2. presents four main expressions and sources of power based on the work of VeneKlasen, as summarized by Lehman and Gilson (2012), into which I have added other key aspects of power from literature (Long 1999; Kaler and Watkins 2001; Lukes 2005).

Table 9.2: Four expressions and sources of power adapted from Lehman and Gilson (2012)

Form of power	Definition
Authoritative power (power over others)	It involves taking power from someone else, and using it to dominate and prevent others from gaining it; Based on one's hierarchal position within social and organizational systems;
Discretionary power	Includes finding common ground among different interests and building collective strength;
Power to act	The unique potential of every person and social group to shape their life and world and create more equitable relations and structures of power;
Power within	People's sense of self-worth, values and self-knowledge;

	Also refers to agency power, the ability for each individual for self-determination; The power to make own judgements and make choices based on prevailing circumstances;

Of interest in the Lehman and Gilson (2012) study are the discretionary powers of facility managers, people at the frontline of policy implementation who are often assumed to be 'powerless' because of their roles of implementing policies according to guidelines and directions of those above them. The study showed that the interface position these staff occupied, and their roles of translating, interpreting and implementing policies gave them discretionary power in policy implementation processes. These powers were used to shape and alter the policy to suit circumstances on the ground. In contrast, health managers appeared to draw on authoritative power which they had due to their hierarchical positions in the health ministry and through budget controls. Some ended up circumventing policy goals and slowing down the implementation processes.

In subsequent sections, I draw on these concepts to discuss some of the forms and expressions of power that emerged in this research. Since I did not specifically set out to investigate power, there are some caveats to the following discussion. Firstly, some of the covert and subtle forms of power can only be inferred from the way some respondents discussed key issues of interest in my research, or as underlying reasons contributing to observable (overt) expressions of micro-level negotiations. Secondly, I can only infer some elements of conflict of interests (Lukes 2005) between different actors based on how they were expressed or discussed, or on the actions taken. This might differ from respondents' views of whether those issues were real conflicts of interest.

Within Household power relations

Authoritative power (power over others) in households was largely described as held by male household heads over other household members, from elders to younger members, and from older women (such as first wives) to younger female (and male) household members (see 6.3.1). This form of power appeared to work in practice in some households, and on certain occasions, but not in others. Thus, some female household members and minors appeared to challenge male dominance in situations where they felt their choices mattered (see 7.2). Some factors that appeared to influence household negotiations, which Kandiyoti referred to as 'contextual conditions' (Kandiyoti 1988), included how research participation was likely to affect gender roles in the household, and who took responsibility for research activities, and for risks associated with research participation and involvement in KEMRI activities (6.3.2).

It was evident in this research that where women strongly felt that their choices were not considered by those in authority in households, they used various strategies to influence decisions in their favour. Against a backdrop of often dire consequences for women defying household heads' and/or husbands' decisions and authority (6.3.1), women negotiated their preferences and choices, either passively or actively, in ways that - as much as possible - helped maintain harmony in key relationships (Kandiyoti 1988). The strategy of silent refusal, (revisited below) and of 'exploiting' male FWs' vulnerability through 'flirting and seduction (8.4.2), were some of the observable defiance strategies used by some female household members to manipulate research decisions in their favour. Passive strategies included cultivating positive relations with household decision-makers, and altering information shared about a study in an attempt

to increase support for their choices; for example, exaggerating benefits (for consent) or risks (for refusal).

Kandiyoti's (1988) concept of bargaining with patriarchy appropriately frames some of the strategies women used to resist male dominance in some aspects of the research (Kandiyoti 1988). Probably because of the covert nature of silent refusals (unexpressed refusal), those with authoritative power (such as husbands, household heads and male household members) expressed helplessness when they encountered it (6.3.3). The phenomenon of silent refusal suggests that, at least in the Kilifi study setting, participants' choices about research participation are influenced by the way the research is likely to shape relationships with significant others in the household. It was used to circumvent unpopular research decisions, and to manoeuvre personal preferences into decision-making processes, while also maintaining harmony in key relationships.

Participant-FW (and study) relations

With regards to power in participant-FW relations, generally it seemed that FWs were respected in the community due to their being employed in a reputable organisation (KEMRI-WT) and having access to resources, technical knowledge, information about the study and access to the PIs. In addition, the ability of FWs to negotiate for minor changes in study procedures, particularly for the expansion of study benefits, appeared to consolidate their power status among participants and in the community. Participants thus seemed to think of FWs as community gatekeepers and expected them to put community interests over and above those of KEMRI-WT and of research. FWs were likely to be aware of these expectations, and may have encouraged them to achieve their own goals, as has been documented elsewhere (Geissler 2005). Some FWs also

used discretionary power during research implementation to shape research conduct, and to influence perceptions of community members and PIs about them, and about the study. Thus, overall, one would expect FWs to have power over participants in their interactions.

Participants in the two case studies were aware that it was important for them to follow study procedures consistently if the research were to be successful. This was discussed in various forums including in community engagement meetings, during consent processes and at study follow-up visits. They also knew that FWs' job performance largely depended on their participating faithfully in the research (8.5.2). It therefore seems that participants had latent power (Lukes 2005) to influence research conduct, through their ability to determine whether the study would take place (and in what form), and whether FWs would be welcomed to their homes for study follow-up visits. They exercised these powers in various ways; overtly through continuous discussions and requests for additional and different sets of benefits, and through seeking clarification about the study and changes in some of the unpopular procedures (7.2). More covertly, silent refusals (see 7.3) emerged as subtle form of power used by participants in research negotiations.

The practice of silent refusal showed that participants could determine their participation levels (what study procedures to participate in, when and how), and the overall research implementation. Exploring factors underpinning silent refusals shows an intricate interplay between multiple sources of power amongst participants and FWs (7.3.2) that shaped decisions about research participation. Long's (1999) description of agency power appears to be reflected in silent refusals.

> "[Power] is the outcome of complex struggles and negotiation over authority, status, reputations and resources .... such struggles are founded upon [the] extent to which specific actors perceived themselves capable of manoeuvring within particular situations and developing strategies for doing so" (Long 1999 p2).

Together, these factors contributed to participants' perceptions and understanding of their tacit power to control the direction of study implementation, while maintaining harmony in key relationships. I call this subtle power as it was not explicitly expressed and appeared scattered and fragmented across different participants and over time. The relational nature of this form of power made it difficult to detect in the first instance, and was frustrating to those who experienced it (8.2.4).

Another dimension of subtle power of participants over FWs emerged by examining the vulnerable positions of male FWs in interactions with female household members. FWs entering into participants' homes and carrying out study procedures placed them in social spaces of intimacy within the households. That the gender of FWs interacting with participants matters in the conduct of research is discussed in the literature. This has been reported for qualitative interviews (Streeton, Cooke et al. 2004); in participant recruitment and follow-up (Shagi, Vallely et al. 2008; Simon and Mosavel 2010; Mosavel, Ahmed et al. 2011); and as part of respecting cultural norms (Papadopoulos and Lees 2002; Marshall 2008). In the two case studies in this thesis, there were few female FWs (3/10 and 1/26 in CSA and CSB respectively), which was a concern for some participants. The conduct of male FWs in households was scrutinized with any inkling of 'misconduct' likely to influence how they were viewed and discussed in the households, and potentially reported to their supervisors; where 'misconduct' included

being overly friendly to female household members, or in some cases appearing to give financial assistance to married women in the absence of their husbands (8.4.2). Local cultural norms on bodily contact across different gender and age groups are highly respected in the community. Some study procedures (such as taking of temperature, and of NFS) required FWs to manoeuvre around the local norms; with many male FWs reporting having to seek permission from household authorities before carrying out such procedures.

In addition, circulating rumours of male FWs misbehaving in the community (see 5.2.3) seemed to heighten male FWs' vulnerability in households. Emphasis placed on appropriate behaviours during FW induction training may have increased their sense of caution. The cultural practice of *malu,* the punishment of paying fines for adulterous males found to have engaged in sexual relations with married women or girls (8.4.2) may also have contributed to male FWs feeling particularly vulnerable while interacting with female household members. These factors contributed to male FWs' feeling anxious and helpless in situations they would ideally have institutional authoritative power over participants.

Possibly unexpectedly, vulnerability for female FWs was less pronounced. This may have been due to low number of female FWs employed in community-based studies generally and in the two case studies in particular (see 5.2.2). Possibly, female FWs may not have been seduced by male HH members or they may not have wanted to make a big deal of it. They may also not have felt free to raise seduction as an issue in interviews and discussions. In addition, seduction is often assumed to be a male domain, with female FWs less likely to be accused of seducing male household members. On the other hand, being seduced by male household member can place

female FWs in potentially vulnerable positions especially where unwanted attention could lead to risks of physical harm. Consideration of these issues contributed to the research centre approach of often deploying female FWs to office-based and ward-based research activities (see 5.2.2). While the research centre's approach may seem appropriate, it could potentially be used to deny female FWs opportunities to work in community-based studies. A commitment to fairness in employment of FWs would require research centres to have policies that address structural factors that may disadvantage either gender in employment, especially where studies show that gender of a FW is an important factor to consider in research interactions, as was shown in my study.

Fieldworkers – Principal Investigator (PI) power relations

The hierarchical position of PIs as the primary study investigator and employer of the FWs put them in a position of authoritative power over FWs (and other study team members). Some PIs appeared to exercise this power through strategies aimed at securing FWs' compliance with guidelines and rules, or in how they handled issues on which they appeared to differ. The coercive overt strategies used included threats of potential loss of jobs during FWs' probationary period and of being fired for not performing as per expectations. As described in 8.5.2, performance charts were thus seen by FWs as tools to be used by PIs to justify termination of a FW contract, and not necessarily as a tool to assist in identifying key areas that FWs needed support with.

In both case studies, however, FWs' advice was either expected or actively sought by PIs on a number of issues. FWs were therefore in positions to filter what went up the 'system' and what did not; for example, some FWs chose to seek opinions from their peers rather than from supervisors on how to resolve some challenges they faced (see

8.5.1). Lehman and Gilson (2012) alluded to the discretionary power of the frontline managers implementing a CHW policy in South Africa, as power to

> "...shape the implementation of the CHW strategy ...in ways that thinned down and subverted complex multi-faceted policy intentions and generated unintended outcomes" (p2).

It seems that FWs were also having to choose between different goals, including: meeting research goals and interests; being the channel by which their community and the participants could benefit (develop) from KEMRI-WT (8.3), and their own career advancement and development goals. These varying goals seemed to underpin the way in which support systems were used. Thus, if the use of support systems was likely to undermine a FW's career advancement, he/she was likely to use alternative ways to resolve the issues, sometimes with undesirable outcomes for the research (see 8.5). Lehman and Gilson (2012) make the claim that even in situations of limited decision-making power for frontline staff, they can find ways to create power positions, including information bottlenecking and tinkering with policy requirements. FWs were not expected to have power or control over the direction of the study, rather, they were expected to carry out their main roles according to study SOPs, and to refer challenges they encountered up the hierarchy. However, the above points, together with the findings in empirical chapters, clearly show that FWs were in unique positions to make decisions that would affect how they were perceived by the PIs (and other study teams), and the way the study was shaped and implemented in the field.

Research institution – community relations

While this research did not aim to explore the nature of relations between the research centre and the community, previous studies have alluded to power differentials in this

context as a result of inequalities in resource, wealth, technology, skills, knowledge, local and global connections, among others (Molyneux, Peshu et al. 2004; Molyneux, Wassenaar et al. 2005; Marsh, Kamuya et al. 2008). Such differences are described for other research centres (Fairhead, Leach et al. 2006; Geissler 2011). These factors can lead to research institutions being perceived by local residents/communities as having high levels of control over research activities and of the way communities can be involved in those activities. To a large extent, research ethics guidelines and the regulatory frameworks (including the ethics review committees) help regulate extant powers of research centres over communities involved in research activities. In addition, recent reviews of research ethics guidelines at the research centre aimed at addressing some of these power differentials through strengthened informed consent processes, community engagement practices, and revised benefit-sharing guidelines (see 3.6). Nevertheless, a well-resourced and wealthy research centre situated in a generally poor rural community might inevitably appear to have more power than the community members with whom researchers interact.

A deeper look at some of the stories around KEMRI-WT (5.2.3) and its research activities, however, shows the immense potential for the community to influence research activities in this setting. Rumours surrounding research activities are widely discussed in the literature, as a defiance strategy by communities in response to health and wealth inequalities, and historical injustices (Geissler and Pool 2006). As Geissler et al points out, rumours reflect:

> "...scepticism of those who tell these stories, their ambiguity towards formations of knowledge and power that reach deep into their everyday lives and which are set in a world order that provokes their doubts (Geissler and Pool 2006 p975).

The potential negative effects of rumours on research conduct and relations between the research centre and the community partly contributed to the set-up of systems to support research conduct in the two case studies (3.6.1). Thus, advice was actively sought from FWs, CAST teams and community leaders where there were stories or rumours about KEMRI-WT or the research circulating in the community.

In addition, the nature of research negotiation described in this study shows that participants (and communities) were becoming aware of their role and importance in research. Thus, communities could negotiate for their own interests such as employment of their members in research activities (see 5.2.3). Such demands seem to point to a transactional model of research negotiations where participants and communities can voice their demands at the onset of research, and researchers can discuss whether or not they can meet them (Wertheimer and Miller 2008; Friedman, Robbins et al. 2012). Of particular interest for research ethics is then how to safeguard the spirit of goodwill and altruism in research so it does not get eroded by commercializing research participation (Wertheimer and Miller 2008). One way is to draw on the powers of participants and communities positively to influence policies through building collaborative partnerships with communities, as discussed in 9.4.

These factors point to vulnerabilities for research institutions in working with communities, though the form and type of vulnerability may change over time and across settings. The supposedly powerful position of research institutions can be counterbalanced (to some extent) by research participants if studies are to be successfully conducted. Recognition of these power positions and vulnerabilities is important in informing community engagement processes, research ethics discourses and understanding of the micro-level factors that influence research interactions. FWs

at the interface of research implementation, confront these micro-practices of power in a personal way. I therefore discuss their roles as imbued with moral issues next.

9.3.4 FWs are doing ethics in the field: interface roles of FWs

The unique position of FWs at the forefront in research implementation means that they have multiple roles and interests: as gatekeepers of the community they come from and work within; of cultural brokerage for the research that employs them; and their own interests (to advance their careers, and maintain a certain status in the community). It also places them in positions of both power and of vulnerability (as discussed above). The way they mediate between these multiple roles, power positions and interests is important for culturally sensitive and ethically sound conduct of research.

Some interest and attention has been given to cultural brokerage in research conduct, especially with regards to informed consent processes and the ethical conduct of research (Molyneux, Peshu et al. 2004; Marshall 2008; Tekola, Bull et al. 2009). Cultural brokerage, one of the roles of FWs at the interface of research implementation, includes bridging and mediating between different cultures and norms in order to minimize conflicts, more so in international collaborative research where the norms of the researchers and those of research populations may be different (Marshall 2008). Interface analysis recognizes the ambivalent position of individuals working at the interface "since they must respond to the demands of their own groups as well as the expectations of those with whom they must negotiate" (Long 1999 p2).

FWs appeared to work through their multiple roles of interfacing between researchers and participants and being cultural brokers, in interesting ways. Where protocols were

unclear on the course of action to take, FWs appeared to make pragmatic choices, drawing on the local social norms and value systems in handling some of the challenges they encountered (see 8.2). They, therefore, appeared to operate similarly to street level bureaucrats defined by Michael Lipsky in 1980 as, "public service providers who interact directly with citizens in the course of their jobs, and who have substantial discretion in the execution of their work" (Lipsky cited in Pierre and Peters 2003 p153). The nature of street level bureaucrats (as frontline implementers of public policy) and conditions of their employment, (with less direct supervision, necessity for responsive decisions, and constrained resources), brings dual capacities of discretion in decision-making and ability to respond to specific demands of work (Lipsky cited in Kaler and Watkins 2001). Street level bureaucrats' behaviours vary widely, with some being client-centred (Kaler and Watkins 2001; Prendergast 2007), while others are self-interested, focussing on establishing their authorities and powers within the public. Others still are simply keen to preserve their jobs and be seen to be doing a good job by their superiors. This categorization is not mutually exclusive, with individuals showing all of these behaviours across time and space (Kaler and Watkins 2001), as was the case for the different types of FWs employed at the research centre. The unique position for FWs, of being socially embedded in the community (Geissler and Molyneux 2011), makes the way they carry out their research roles important for the ethical conduct of research.

The social embeddedness of FWs in their community appears to have influenced the way FWs responded to participants' issues, fears and concerns. FWs wanted to respond in ways that allayed participants' fears whether or not that resulted in continued participation or better understanding of KEMRI-WT. Participants, as individuals and fellow community members, therefore mattered intrinsically to many FWs. This in part

contributed to the emotional distress felt by some FWs when they could not offer more benefits to participants who were in need of such assistance. It also may have contributed to allowing silent refusals to remain in the study when they should have been dropped as per study protocol. This implies that FWs' conduct were not always about following study guidelines, SOPs and training, but also FWs' own judgements of what felt to be right at the time, including as a result of their relational responsibilities. FWs could therefore be said to be doing moral work (Parker 2012).

As moral agents, FWs were having to manoeuvre between various interests and goals, while also appearing not to openly contravene study regulations and local norms. Where interests or goals did conflict, these presented as dilemmas to FWs, who had to choose between various suboptimal choices. FWs therefore needed to delicately balance between duty to their communities, to the study and to themselves. Their roles required of them to address divergent interests, perform well in order to stay relevant and maintain their employment as well as to be viewed positively by the PIs, supervisors, communities, peers and their families. Each of these micro-level interactions required FWs to use various skills, and to make judgments of what was the right thing to do at that time, a practice that Parker has referred to as moral craftsmanship (Parker 2012). Understanding how FWs work through various issues and conflicting interests starts to unpack the moral world of FWs at the frontline of research implementation, and consider the relevance and practicality of their roles for research ethics, and the type and nature of support they require.

9.3.5 Revisiting the conceptual framework

In section 2.6.1, I described the conceptual framework that I developed to guide the design of this research (see also Figure 2.4). In Figure 9.1, I present the conceptual framework with more information based on the empirical findings of this study and the discussion of the key emerging issues. The revised conceptual framework provides closer focus on the micro-level interactions of FWs with participants and the outcomes regarding decision-making for research participation and relationships. These are positioned within wider institutional (meso-level) influences and broader implications for research conduct. I briefly describe each component in turn.

Regarding the meso-level/institutional component, aspects given greater emphasis now are the integration of FWs into functional systems of the research centre, including whether FWs have a sense of belonging to the research centre, and how valued they feel. These factors appeared to influence, and in turn were influenced, by the nature of micro-level interactions.

Overlapping *factors that appeared to influence micro-level interactions* were intra- and inter-household negotiations for research and FWs roles in research activities. Intra-household negotiations involved weighing up several factors, including what the research was really about (the condition being studied), responsibility for research-related activities, norms around decision-making and the extent to which individual choices were accommodated. For FWs, some of the factors that appeared to influence their interface roles included the nature of their roles, competence in their jobs, opportunities to improve their skills (for example, through on-the-job training), ability to recognize and handle different challenges, being able to know when and where to

seek support, and availability of responsive support (including recognition for their performance).

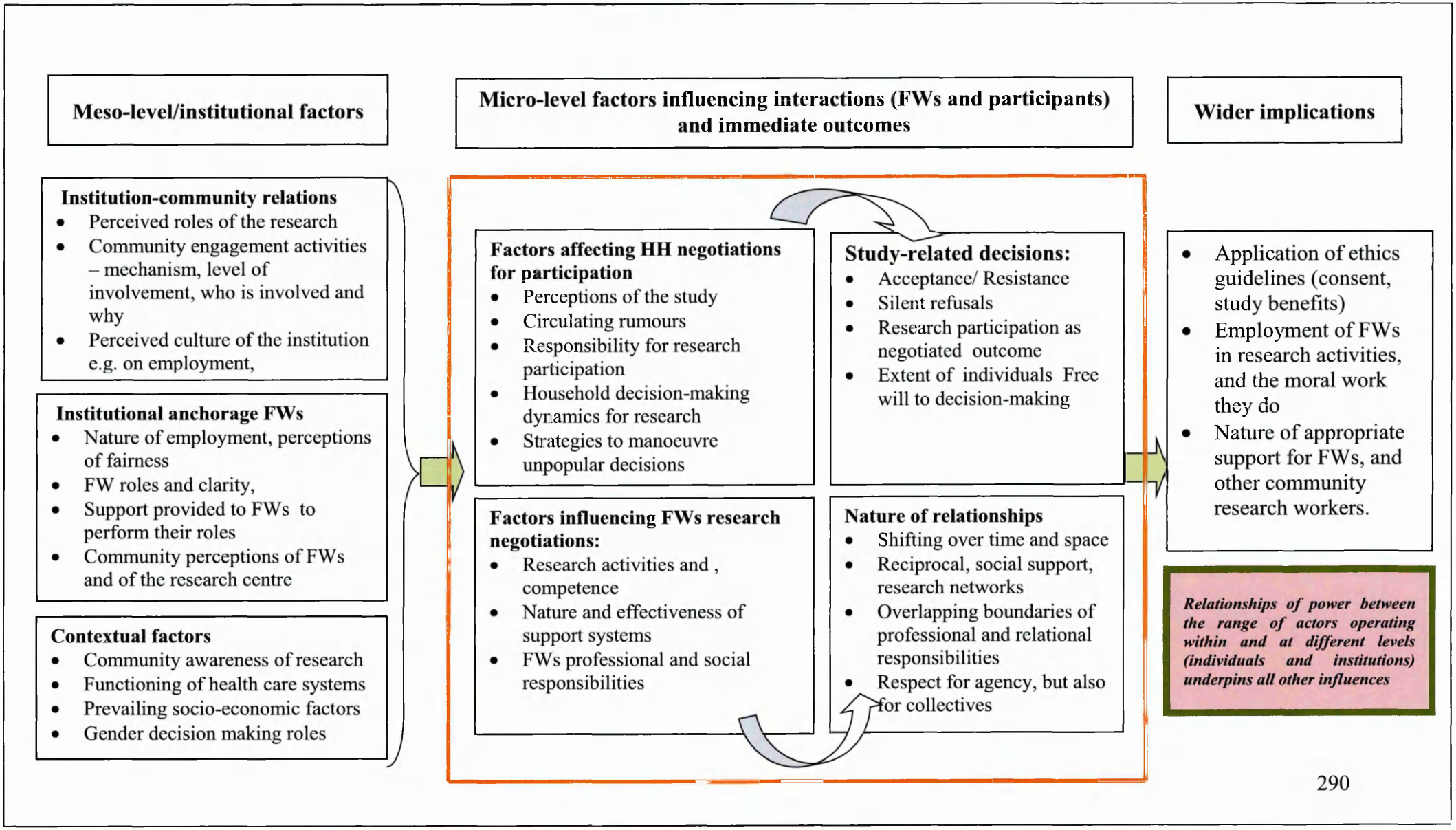
Taken together, these factors appeared to affect two *immediate outcomes,* type of research-related decisions by participants, and nature of relationships between FWs and participants. At the micro-level, research decisions influenced and were influenced by the nature of relationships within the household, with FWs and within the wider community. Research participation appeared to contribute to development of new social networks, through participants and FWs being connected by the shared experiences of the research; and relationships having been nurtured throughout the study. Study benefits acted as a form of social support, particularly for the most needy families. Sensitivity to the nature of relationships was important for research decisions. For example silent refusals appeared to be about safeguarding relationships with significant others (avoiding social strain in the network), while allowing participation in research in ways that were favourable for the participants, and possibly for even the study teams.

The *wider implications* of micro-level interactions and outcomes include how ethics guidelines are applied, how FWs do their work including the moral aspects of their work and how they could and should be supported.

An important backdrop for all these activities, their influences and the outcomes experienced is a complex *interplay of shifting power relations* (highlighted in the coloured box). Power relations were seen in negotiations within households, with participants and FWs, within the study teams and within the overall institution (as

discussed in 9.3.3). This is an area that is clearly crucial for FWs at the interface of research implementation.

Figure 9.1: Revised conceptual framework - factors influencing FWs' interactions with participants, and the immediate outcomes and wider implications



9.4 Recommendations on the nature and type of support for FWs

This section addresses the last objective of this research: Objective 6*: To develop recommendations for supportive supervision of fieldworkers in this and other similar settings*. The recommendations suggested move forward some of the institutional level issues with regards to FW roles and support, while recommendations regards the more theoretical areas of research ethics with particular focus on informed consent and study retention. I however, first reflect on generalisability of the study, because of the implication of the recommendations I suggest. This is in addition to methodology generalisabilty described earlier in 4.7.

9.4.1 Generalisability of the study findings

Ritchie and Lewis (2009) discuss three types of generalisation in qualitative research (Ritchie and Lewis 2009, p264-286).

- representational generalisation, which is the extent to which the findings of the research can be generalised to the population where the research is conducted;
- inferential generalisation which is the extent to which the findings of the research can be transferable or generalisable to similar settings and contexts elsewhere; and
- theoretical generalisation, which is about application of theoretical explanations that emerge from a study.

The thick description of the context and the study methodology described in chapters 3 and 4 aimed to provide information that can aid the reader to gauge the extent to which the findings of this study can be transferred to other settings. In 4.7, I discussed the various approaches taken to strengthen representation generalisation (for other studies

and FW groups within KEMRT-WT) and inferential generalisation (across similar settings). The approaches used to support theoretical representation included:

- providing information on the theoretical and interpretative framework used in this research (see1.3 and 1.5);
- description of the methods used, selection of the respondents, analysis process, triangulation aimed to allow dimensions of the theoretical concepts to be tested elsewhere (discussed in Chapter 4), and;
- reference to the international literature for emerging concepts, as discussed in section 9.3;

Generalisation to other forms of *community researchers* (see 2.5) might depend on how embedded they are in the community and in the research centres, the nature of the study they are involved in and their roles, the nature the research institution and how long term and large it is; and the nature of initial training and support systems available. Some issues that were of great concern to FWs in this study such as career progression and job security may be subdued or irrelevant for others. Some of the ethical issues such as levels of persuasion for research participation are likely to be relevant to all types of participant recruiters. These caveats need to be taken into account in considering subsequent recommendations.

9.4.2 Institutional level recommendations

FWs are clearly in the forefront of research implementation, they therefore require appropriate levels of support and skills competence in order to carry out their roles appropriately, and for the credibility of the science (in ethical conduct and quality of data) to be upheld. I propose three areas that studies and research institutions need to consider carefully.

Supportive supervision for FWs

It has been recognized in health care that in addition to regular structured supervision, there is need to provide supportive supervision to staff. Margue and Kean cited in PATH[74] defined supportive supervision in health care as "a process that promotes quality at all levels of the health system by strengthening relationships within the system, focusing on the identification and resolutions of problems, and helping optimize the allocation of resources ... promoting high standards, team work and two-way communication" (PATH 2003 p8).

Supportive supervision includes regular structured supervision where individual performance is assessed against targets, and key areas of monitoring are identified in advance. The added value of both supportive and regular supervision is the opportunity for one-on-one feedback, on-the-spot response to field issues, and a deliberate focus on both performance appraisal and individual growth (PATH 2003; Bogo, Paterson et al. 2011). Skills and management styles of the supervisor and of the PI are important to the way supportive supervision is understood and implemented. This may require both immediate supervisors and PIs to spend considerable time in the field, more so at initial stages of setting up a study. Additionally, specific training tailored to the needs and skill-sets for FW supervisors, coordinators and managers can be organized periodically. It is important for FWs to have appropriate skills to be able to identify ethical dilemmas, and when and where to seek support.

[74] PATH - Program for Appropriate Technology in Health;

Principal Investigators (PIs) are a key group in the way FWs and their supervisors do their work. As well as paying attention to research protocols, recruitment and retention, they need to be seen to be taking issues from the field seriously. Sensitivity to target monitoring is needed, including a balance of paying attention to study targets and the supporting ethical conduct of the research. Where FWs are under considerable pressure to meet targets, researchers should reflect on the implications. Amendments might be needed, including negotiating with research review mechanisms for extensions of study recruitment periods if FWs are facing low acceptability of the study. Equally important, but not dealt with in detail in this research, is the FW individual characteristics and qualities that could promote or undermine research, which could be informed by virtue ethics lens. There is increasing attention now given to qualities of a good researcher, a similar attention could also be given to FWs.

FWs' experience sharing forum:

Borrowing from the model of the Genethics Club initiated over 10 years ago to deliberate ethical issues around genomic research (Parker 2012), FWs forums for experience sharing across different research groups and teams could be an additional support system. The forums can be organized by the FWs themselves and facilitated by people with appropriate skills and experience, and be independent of the studies the FWs are involved in. In our programme, community facilitators based in the Community Liaison Group would be ideal. Having an independent facilitator is important in ensuring that FWs feel free to share field issues and challenges, even those they would otherwise not inform their immediate supervisors about for worries of losing their jobs. Facilitation skills for moderators are necessary, but perhaps more importantly, is a good understanding of current ethical debates, and competence to link

issues from FW forum with appropriate institutional structures, and with wider relevant debates. Given that KEMRI-WT has nearly 300 FWs, a suggested approach to organizing the FWs' forums would be based on key issues emerging from the field (for example, minors' assent, issues with study benefit distribution), or based on types of studies FWs are employed in (for example, those studies involving blood sampling, or requiring sensitive information from participants).

Professionalizing field work career

Emerging from this research is that many of the FWs were employed for the first time in the research centre and clearly required appropriate support to do their work well. Institutional systems that provide career progression, and promote transparency in promotion would provide some level of stability for FWs. Short term funding limits the extent to which a structured career pathway can work because researchers also have short term funding. However, the same arguments also hold true for researchers, yet there are career progression pathways for them. For long-term research institutions like KEMRI-WT, it has been possible to keep many FWs for years. A clearly articulated system for progression is important to provide fairness, clarity and motivation for FWs. This is currently being discussed at the research centre. Additionally, attention needs to be given to local sensitivities in employing such staff, for example with regards to FW gender and ethnicity.

9.4.3 Implications for informed consent and consenting processes

Voluntariness: taking social contexts more seriously

The way in which an individual's decision for research participation is negotiated and respected in studies is an area of ethical concern. This study showed that the process of

gaining individual informed consent needs to consider carefully background situations such as the place and space for individual choices within a household. This is especially the case in our setting where male-headed extended households are common, as well as for largely patriarchal or communitarian (with a recognized leadership hierarchy) communities. As was shown in this study, there is potential for individual choices within households to be silenced, more so for 'disenfranchised[75]' household members such as minors and females, especially where decisions differ significantly from those of male adult household members and household heads. This suggests that prior engagement at household level before consent is important; to create awareness about the importance of individual choices in research; to discuss cultural sensitivities of the research; and to find ways to minimize tensions between ethical requirements and cultural norms.

Household consenting processes: embracing negotiations and consultations

Related to the above, this research showed that individual's choices are negotiated at the household level, and that sometimes the choices made are aimed at safeguarding intra-household relations, rather than individual preferences. There are potentially perverse outcomes, however, if focus on individual choices fails to encapsulate the household dynamics that influence those choices. The recent Nigeria study (Osamor and Kass 2012) suggests that decision-making for research is a relational activity. This area, needs to be further investigated in settings similar to ours to inform on the type and nature of household consultations and how to safeguard different interests of household members, including women and minors, in consent processes.

[75] I use the term to refer to those members in a household that are according to customs and norms not expected to have much say in what goes in the households, but also recognize that they indirectly influence decisions.

Benefit types, levels and distribution: advisory teams and guidelines

Presence of research activities in a community inevitably impacts on intra-household and intra-community relations. Researchers' sensitivity to these relations requires them to be responsive to community needs and to monitor the impact of research on community dynamics. Providing direct and collateral benefits while desirable, is likely to strain research with small budgets or those with minimal activity with communities, and could potentially lead to intra-community conflicts. On the other hand, long-term research projects and programmes have opportunities to invest in and provide needed support to communities. Careful attention needs to be given to types, levels and distribution of research benefits for different types of studies. Typically, researchers propose study benefits at protocol development stages based on some guidelines (which most institutions in developing countries, including ours, do not have) or on wider consultations with, for example, experienced long term researchers, community opinion leaders, and in our case, community facilitators and fieldworkers. Our focus at KEMRI-WT has been on providing health related benefits to individuals and communities, and developing collaborations and linkages with other implementers where necessary (Molyneux, Mulupi et al. 2012). In the case of health related emergencies such as the cholera outbreak discussed in this study (for case study A), the response has been to work alongside, and provide support to the Ministry of health. The challenge has been for FWs facing humanitarian cases such as famines, drought, and floods. There has been a suggestion that certain percentage of each research budget can be set aside to address community needs. This appears to support Ballantyne's proposal of an infrastructural charge (Ballantyne 2008). These funds can then be pooled into a research fund that supports community needs including emergencies and humanitarian

aid, in line with a proposal by Lavery et al (Lavery, Bandewar et al. 2010). Working collaboratively with other organizations to provide such aid to communities is one approach which has been proposed in our research centre (Molyneux, Mulupi et al. 2012). There are advantages for working with such organizations: it could minimize potential for community members to conflate the work of the research institution with that of an aid organization (as is likely to be the case at our research centre); the aid organization would have technical skills and logistical capacities to deliver the aid to the community; and working with them will take relatively less time out of researcher's core business of doing research than would be the case if researchers were directly involved. An alternative approach is for research institutions to set-up semi-independent departments to handle humanitarian aid, collateral benefits to research communities and social responsibility, especially where there no alternative collaborators, or where accountability mechanisms for those institutions are weak. Regardless of the system used, there is need to consider carefully implications of such humanitarian systems on research conduct and on existing community social networks.

In our case, having CAST groups (see 3.6.1 for description of CAST) were helpful in giving an 'outside'[76] advice to research team facing field challenges, including those regarding study benefits; as well as advising on community engagement activities. The CAST supplements institutional and national ERCs in ensuring that levels and types of benefits being offered by individual studies are appropriate, given that ERCs at national level are often unable to take into account local day to day issues and concerns. As was evident in this research, it is important that CAST members are sensitive and

[76] Some members of the CAST team, the community liaison group members, are considered outsiders to the study because they are not directly involved in the day-to-day activities of the research; and would be expected to have a relatively objective view of study requests.

responsive to issues emerging from the field. Balancing being objective and sensitive to field situations is not easy. One way to facilitate this would be for 'outside advisors' such as CAST members to spend some time with FWs in their field activities. This would add depth to their discussions and considerations.

Another suggestion is that FWs could be provided with a 'tsunami[77]' fund to assist cases they encounter in the field (Molyneux, Mulupi et al. 2012). However, this has its' own potential to raise new problems around how fieldworkers would decide whom to offer assistance, how to ensure fair distribution of the assistance, the potential impact on FW power relations with particular individuals and households, and households' ability to refuse or withdraw from the study. Moreover, there is the potential for such short-term strategies to leave the families worse-off post-study end by displacing some other forms of support that families draw on. FWs might feel compelled to help more needy non-participants, failure of which might exacerbate the transient inequities research participation appears to present in communities. In case study A, were many households were in need of assistance, the need for assistance was not a once-off emergency but more of a background situation for many households. While these areas are being deliberated at the research centre, there is need to take consider benefits, including collateral benefits, beyond individual participants involved in research, and beyond the narrow-focus of a specific research (Ballantyne 2008; Lavery, Bandewar et al. 2010).

[77] An amount of money that they can use to address cases that are desperately in need of assistance. It has been suggested that this fund can be raised from each research grants, as a certain percentage.

An alternative, potentially more acceptable approach is to link such support to other institutions with the remit to provide assistance such as NGOs, government departments, and CBOs operating in the area. A challenge, however, is the ability and sustainability of those institutions. The dilemmas remain: on how far researchers should go in addressing real needs of community (beyond health-related needs), and how should they do so in ways that the end of the research does not leave the community in a precarious situation.

9.4.4 Implications for community engagement processes

The approach of community engagement used by many research institutions, including KEMRI-WT has been to provide information, set-up and support forums for consultations (for example. CABs) and increase interactivity between researchers and study populations (Marsh, Kamuya et al. 2008; Kamuya, Marsh et al. 2013). This research suggests that FWs daily interactions is part of community engagement activities and that it should be taken seriously, including being formally recognized as part of their roles, and ensuring they are appropriately supported. These issues also need to be considered in frameworks of community engagement.

Community-based participatory research is another approach in which community members are involved as partners in a research activity around a health issue that is a priority to them, and where they are involved to varying levels at every stage of the research (Minkler 2005; Cashman, Adeky et al. 2008). Involving communities in this way is an opportunity for meaningful engagement and relatable experience with them (Wallerstein and Duran 2006; Vallely, Shagi et al. 2007), and could underpin understanding of research among the communities. However, the hugh cost of such

activities, raised community expectations, threat to scientific validity of the research and ethical considerations are some of the issues that need to be considered carefully (Mosavel, Simon et al. 2005; Simon, Mosavel et al. 2007). As discussed in 2.2.2, it is important to consider the goals of engagement, the communities and the depths of meaningful community engagement.

9.5 Contribution of this research to knowledge

This research provided insights into issues that FWs face in performing their roles in a developing country setting. I am aware of only two sites in Africa that in the last 2-4 years, have studied the ethical work of FWs or their variants. One site is Western Kenya, with two doctoral theses submitted in the last one year by Patricia King'ori and Tracey Chantler (the latter focused on village reporters). The other is the work done by Simon and colleagues, which has been referenced in this research. Both sites are contextually different from the Kilifi site.

This thesis shows the messy realities for FWs doing research within their own communities. In particular, it shows that research participation is negotiated throughout the course of research. The nature of negotiations can help support ethical conduct of research through shared understanding, but can also undermine the conduct of that research if people feel less free to make choices. Silent refusal emerged as an issue of ethical concern, straddling between nature of relationships with significant others, access to study benefits and consent decision-making processes. While conceptual papers have hinted at similar concepts such as social solidarity (Lindegger and Richter 2000), I found no literature that discussed the concept of silent refusal in regard to research participation.

Secondly, this research showed the intricacies involved in negotiating for entire household consent and participation in research. Few studies in Africa have looked at negotiations for research involving entire households; genomic studies and population-level public health studies are some of those that provide information on informed consent beyond individual level. Using a social science lens, this study showed the interplays of agency and power for both individual and household level consent and continued participation in research. The issues raised in this research need to be carefully considered with regards to recruitment and retention strategies for research.

Thirdly, this research showed that FWs are doing moral work at the interface of research implementation. Working within, and being socially embedded in the communities where research is happening, has strengths and also presents ethical challenges and dilemmas for FWs, with FWs adopting responses based on ground realities. Some of the ways they respond to challenges can appear exploitative, but this need to be considered within the settings and the contexts that FWs work in (Kamuya, Marsh et al. 2011). For example, while persuading participants can be a form of horizontal exploitation (Bean and Silva 2010; Phillips 2010), it also needs to be understood within the context of where and how research is discussed. There are many compelling arguments in the literature, and from this research, for employing FWs into research activities; however, appropriate levels of support should be provided for them in order to build skills to discern and address ethical dilemmas they are likely to encounter in research implementation.

One of the ethical challenges for FWs working in contexts of health and wealth inequalities is the extent to which they can respond to livelihood struggles of some of the community members. Providing humanitarian assistance is suggested as one way to respond to background inequities. FWs, being conduits of such assistance, can potentially be put in ethically challenging situations; they would be best placed to know what form of assistance is required and by whom based on their insider information of the community, but this approach may also inappropriately raise their power status in the community. What starts out as a response to ground realities can be seen, or turn out to be, exploitative in other contexts (Landy and Sharp 2010) requiring careful consideration and weighing up of ethical issues.

In this research, initial mistrust in the research centre meant that, in some cases people did not quickly agree to propositions from the research centre, including those of FWs. There is a level of healthy scepticism in the population which makes community members and participants ask questions, take time scrutinizing the study information, countercheck information given with others and share their experiences of research, all of which appear to influence decisions about research participation. This mistrust is on the one hand good in that it makes researchers and FWs accountable to the community and participants, and encourages diligence in research conduct. On the other hand, mistrust can lead to much time, resource, and energies taken up in research activities (Goudge and Gilson 2005).

9.6 Areas of further research

What I presented in this thesis are the findings of FWs implementing research in one context, a low-literacy economically poor community in the Kenyan Coast. I earlier

discussed limitations to generalizing these findings to other contexts, but also pointed out that some of the theoretical concepts might be applicable elsewhere, which I present in this section.

FWs doing moral work: It emerged that FWs were doing moral work in the case studies, and that they used different value systems to make judgements on appropriate courses of action, especially where there appeared to be tensions between the protocol requirements and local norms, and the conditions FWs were working in. The implications for ethical conduct of research include the extent to which participants' decision making may be hindered or promoted by relationships with significant others, including FWs. It is also possible that these findings emerged because of the context in which this study was conducted. There is therefore a need to explore in other settings how FWs, or variants of these, negotiate for research participation, and the moral work they do.

Silent refusals: In this research, silent refusal emerged as a strategy by participants to determine their participation levels while accessing full study benefits and maintaining harmony with significant others. The ethical implications on the validity of informed consent and decisions on study retention are enormous. While physician-patient relationships are inundated with similar dilemmas, they often appear to be the opposite of silent refusals, that is people readily accept what the physician asks of them, sometimes blindly so. The extent to which silent refusal is exhibited in other societies is uncertain, but that social desirability appears in some of the literature suggests that it does exist. There is need for further research on silent refusals to inform on design of effective guidelines on how to identify and handle silent refusals.

Gender and research participation: Informed consent and research participation inevitably has gendered dimensions. This research showed that research affects the way gender roles are negotiated at household level, that silent refusal, in part, is a consequence of skewed intra-household negotiations because research participation appeared to affect women's time for other household chores. Few studies have looked into gender and informed consent and adherence to research follow-ups.

Power relations in research conduct: As earlier alluded to, power relations have received very little empirical investigation. The focus in research ethics and guidance, to some extent, may mediate against covert forms of power that might be expressed. This research showed that different forms and sources of power are played out at all points of interactions. However, given that this study did not set out to empirically investigate power, well designed research across different contexts are necessary.

Assent for minors: Almost all literature on minor's assent is based in developing countries. The little literature from developing countries appears to focus on parent's proxy consent. This could be because fewer research studies are conducted on minors, but also because it is assumed that parents' consent will suffice. This research highlighted that there is need to consider ways to strengthen assent processes for minors and a need for guidelines around study benefits that can be sensitive and responsive to different household demographics, including those of minors and young children. Studies on different engagement approaches with minors, including those around informed consent, minor's reasons for assenting to research, their understanding

of research, and negotiations in a household are needed to inform practice and research guidelines.

Impact of trials/research on communities: As has been hinted in this research, presence of research in a community is likely to affect people's way of life; it takes people time to participate in research, some of the study benefits such as food items and fare refunds add to the family resource basket, and research can cause jealousies in the community between participants and non-participants. It is possible that research displaces or changes the way social life is organized in a community, for example it may strengthen individual freedoms to make own decisions. It is also possible that research creates social networks organized around research experiences, so for example a cohort of children involved in research may identify with the research institution in ways that creates memories of research experience. While there are numerous studies around study benefit distribution, there is little (or no) empirical research on the effect of research on community institutions during and beyond the study period. This area is especially important given the current increase in clinical trials in developing countries.

Evaluation of community engagement activities: As discussed in 2.3, many research organizations have in the last decade implemented community engagement activities. This research also showed that FWs are in fact doing community engagement, albeit not always in ways that are formally recognized. Efforts to evaluate effects of community engagement appear fragmented and lack a clear framework. Recently, a group of researchers in various fields (ethicists, social scientists, philosophers, community engagement practitioners) started work on a multi-disciplinary evaluation

framework (Participants 2011). It is hoped that this work will inform approaches to evaluate community engagement activities across different settings.

Final word

The essence of research ethics is in the depth of deliberations and the different, sometimes opposite, perspectives and views that enrich it. The findings presented in this thesis have shown the challenges that FWs face in interactions with participants in community-based longitudinal studies, how these were resolved and their implications for ethical practice. It showed that interface roles for FWs presented unique opportunities and challenges, negotiating between local norms and ethical conduct, and between meeting research requirements and being sensitive to participants. It further showed the need for appropriate support for FWs if research is to be conducted ethically, and for quality research data to be collected.

References

(Abdul-Quader, A. S., D. D. Heckathorn, et al. (2006). "Effectiveness of respondent-driven sampling for recruiting drug users in New York City: findings from a pilot study." J Urban Health **83**(3): 459-476.

Ahern, K. J. (1999). "Ten Tips for Reflexive Bracketing." Qualitative Health Research **9**(3): 407-411.

Angwenyi, V., D. Kamuya, et al. (2013). "Working with Community Health Workers as 'Volunteers' in a Vaccine Trial: Practical and Ethical Experiences and Implications." Developing World Bioethics **13**(1): 38-47.

Anspach, R. R. and N. Mizrachi (2006). "The field worker's fields: ethics, ethnography and medical sociology." Sociology of Health & Illness **28**(6): 713-731.

Antonucci, T. C., K. J. Ajrouch, et al. (1999). "Socioeconomic status, social support, age, and health." Ann N Y Acad Sci **896**: 390-392.

Appelbaum, P. S., C. W. Lidz, et al. (2004). "Therapeutic misconception in clinical research: frequency and risk factors." IRB **26**(2): 1-8.

Appelbaum, P. S., L. H. Roth, et al. (1982). "The therapeutic misconception: informed consent in psychiatric research." Int J Law Psychiatry **5**(3-4): 319-329.

Ayres, L., K. Kavanaugh, et al. (2003). "Within-case and across-case approaches to qualitative data analysis." Qual Health Res **13**(6): 871-883.

Bajos, N. and J. Marquet (2000). "Research on HIV sexual risk: social relations-based approach in a cross-cultural perspective." Soc Sci Med **50**(11): 1533-1546.

Ballantyne, A. (2008). "Benefits to research subjects in international trials: do they reduce exploitation or increase undue inducement?" Dev World Bioeth **8**(3): 178-191.

Ballantyne, A. (2008). "'Fair benefits' accounts of exploitation require a normative principle of fairness: response to Gbadegesin and Wendler, and Emanuel et al." Bioethics **22**(4): 239-244.

Baum, F. (1995). "Researching public health: behind the qualitative-quantitative methodological debate." Soc Sci Med **40**(4): 459-468.

Bean, S. and D. S. Silva (2010). "Betwixt & between: peer recruiter proximity in community-based research." Am J Bioeth **10**(3): 18-19.

Beauchamp, T. L. and J. F. Childress (2001). Principles of Biomedical Ethics. Oxford, Oxford University Press, Inc.

Benatar, S. R. (2000). "Avoiding exploitation in clinical research." Camb Q Healthc Ethics **9**(4): 562-565.

Benatar, S. R. (2002). "Reflections and recommendations on research ethics in developing countries." Soc Sci Med **54**(7): 1131-1141.

Benatar, S. R. (2004). "Blinkered bioethics." J Med Ethics **30**(3): 291-292.

Benatar, S. R. (2004). "Towards progress in resolving dilemmas in international research ethics." J Law Med Ethics **32**(4): 574-582.

Benatar, S. R. and T. E. Fleischer (2007). "Ethical issues in research in low-income countries." Int J Tuberc Lung Dis **11**(6): 617-623.

Bergum, V. (2002). "Ethical challenges of the 21st century: attending to relations." Can J Nurs Res **34**(2): 9-15.

Bergum, V. and R. Dossetor (2005). Relational Ethics: The Full Meaning of Respect. Hagersrown, Maryland, University Publishing Group.

Bhutta, Z. A. (2002). "Ethics in international health research: a perspective from the developing world." Bull World Health Organ **80**(2): 114-120.
Bhutta, Z. A. (2004). "Beyond informed consent." Bull World Health Organ **82**(10): 771-777.
Boga, M., A. Davies, et al. (2011). "Strengthening the informed consent process in international health research through community engagement: The KEMRI-Wellcome Trust Research Programme Experience." PLoS Med **8**(9): e1001089.
Bogo, M., J. Paterson, et al. (2011). "Supporting front-line practitioners' professional development and job satisfaction in mental health and addiction." J Interprof Care **25**(3): 209-214.
Boulton, M. and M. Parker (2007). "Informed consent in a changing environment." Soc Sci Med **65**(11): 2187-2198.
Bowden, A., J. A. Fox-Rushby, et al. (2002). "Methods for pre-testing and piloting survey questions: illustrations from the KENQOL survey of health-related quality of life." Health Policy Plan **17**(3): 322-330.
Brieger, W. R. and C. Kendall (1996). "The Yoruba farm market as a communication channel in guinea worm disease surveillance." Social Science & Medicine **42**(2): 233-243.
Bryman, A. (2004). Social Research Methods, Oxford University Press.
Cargo, M., T. Delormier, et al. (2008). "Can the democratic ideal of participatory research be achieved? An inside look at an academic-indigenous community partnership." Health Educ Res **23**(5): 904-914.
Cargo, M. and S. L. Mercer (2008). "The value and challenges of participatory research: strengthening its practice." Annu Rev Public Health **29**: 325-350.
Cashman, S. B., S. Adeky, et al. (2008). "The power and the promise: working with communities to analyze data, interpret findings, and get to outcomes." Am J Public Health **98**(8): 1407-1417.
Cassell, E. J. (2000). "The principles of the Belmont report revisited. How have respect for persons, beneficence, and justice been applied to clinical medicine?" Hastings Cent Rep **30**(4): 12-21.
CDC/ATSDR (1997). "Principles of Community Engagement: CDC/ATSDR Committee on Community Engagement."
Chadwick, G. L. (1997). "Historical perspective: Nuremberg, Tuskegee, and the radiation experiments." J Int Assoc Physicians AIDS Care **3**(1): 27-28.
Chambers, T. (2001). "Participation as commodity, participation as gift." Am J Bioeth **1**(2): 48.
Chavis, D. M. and P. Florin (1990). "Nurturing grassroots initiatives for health and housing." Bull N Y Acad Med **66**(5): 558-572.
Chilengi, R. (2009). "An ethics perspective on responsibilities of investigators, sponsors and research participants." Acta Trop **112 Suppl 1**: S53-62.
Chokshi, D. A., M. A. Thera, et al. (2007). "Valid consent for genomic epidemiology in developing countries." PLoS Med **4**(4): e95.
Christakis, N. A. (1992). "Ethics are Local: Engaging cross-cultural Variation in the Ethics for Clinical Research." Social Science & Medicine **35**(9): 1079-1091.
Christman, J. (2004). "Relational Autonomy, Liberal Individualism, and the Social Constitution pf Selves." Philosophical Studies(117): 146-164.
Chuma, J., L. Gilson, et al. (2007). "Treatment-seeking behaviour, cost burdens and coping strategies among rural and urban households in Coastal Kenya: an equity analysis." Trop Med Int Health **12**(5): 673-686.

Chuma, J., T. Maina, et al. (2012). "Does the distribution of health care benefits in Kenya meet the principles of universal coverage?" BMC Public Health **12**: 20.
Chuma, J., V. Okungu, et al. (2010). "Barriers to prompt and effective malaria treatment among the poorest population in Kenya." Malar J **9**: 144.
CIOMS (2002). "International ethical guidelines for biomedical research involving human subjects." Bull Med Ethics(182): 17-23.
Cohen, S. and T. A. Wills (1985). "Stress, social support, and the buffering hypothesis." Psychol Bull **98**(2): 310-357.
Countries, P. i. t. C. o. E. A. o. R. i. D. (2002). "Ethics. Fair benefits for research in developing countries." Science **298**(5601): 2133-2134.
Cox, L. E., J. R. Rouff, et al. (1998). "Community advisory boards: their role in AIDS clinical trials. Terry Beirn Community Programs for Clinical Research on AIDS." Health Soc Work **23**(4): 290-297.
Coyne, I. (2010). "Accessing children as research participants: examining the role of gatekeepers." Child Care Health Dev **36**(4): 452-454.
Coyne, I. (2010). "Research with Children and Young People: The Issue of Parental (Proxy) Consent." Children & Society **24**(3): 227-237.
Cruickshank, J. (2012). "Positioning positivism, critical realism and social constructionism in the health sciences: a philosophical orientation." Nurs Inq **19**(1): 71-82.
Curtis, S., W. Gesler, et al. (2000). "Approaches to sampling and case selection in qualitative research: examples in the geography of health." Soc Sci Med **50**(7-8): 1001-1014.
Cutcliffe, J. R. (2003). "Reconsidering Reflexivity: Introducing the Case for Intellectual Entrepreneurship." Qualitative Health Research **13**(1): 136-148.
Davies, A., B. Mbete, et al. (2012). "Seeing 'With my Own Eyes': Strengthening Interactions between Researchers and Schools*." IDS Bulletin **43**(5): 61-67.
Davis, L. L., M. E. Broome, et al. (2002). "Maximizing retention in community-based clinical trials." J Nurs Scholarsh **34**(1): 47-53.
de Melo-Martin, I. and A. Ho (2008). "Beyond informed consent: the therapeutic misconception and trust." J Med Ethics **34**(3): 202-205.
De Vries, R., L. Turner, et al. (2006). "Social science and bioethics: the way forward." Sociology of Health & Illness **28**(6): 665-677.
De Vries, R. O. B. and B. Gordijn (2009). "Epirical Ethics and Its Alleged Meta-ethical Fallacies." Bioethics **23**(4): 193-201.
DeJong, J., Z. Mahfoud, et al. (2009). "Ethical considerations in HIV/AIDS biobehavioral surveys that use respondent-driven sampling: illustrations from Lebanon." Am J Public Health **99**(9): 1562-1567.
Delavande, A., X. Gine, et al. (2009). Measuring Subjective Expectations in Developing Countries: A critical Review and New Evidence. Policy Research Working Paper The World Bank. .
Department of Health (2006). Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africal. D. o. Health. Pretoria, South Africal: 96.
Diallo, D. A., O. K. Doumbo, et al. (2005). "Community permission for medical research in developing countries." Clin Infect Dis **41**(2): 255-259.
Dickert, N. and J. Sugarman (2005). "Ethical goals of community consultation in research." Am J Public Health **95**(7): 1123-1127.
Dickert, N. W. and J. Sugarman (2006). "Community consultation: not the problem--an important part of the solution." Am J Bioeth **6**(3): 26-28.

Due, P., B. Holstein, et al. (1999). "Social relations: network, support and relational strain." Soc Sci Med **48**(5): 661-673.
Edgren, K. K., E. A. Parker, et al. (2005). "Community involvement in the conduct of a health education intervention and research project: Community Action Against Asthma." Health Promot Pract **6**(3): 263-269.
Ellis, C. (2007). "Telling Secrets, Revealing Lives." Qualitative Inquiry **13**(1): 3-29.
Emanuel, E. J., D. Wendler, et al. (2004). "What makes clinical research in developing countries ethical? The benchmarks of ethical research." J Infect Dis **189**(5): 930-937.
EPDC (2007). Kilifi: Kenya District Primary Education Profile, Education Policy and Data Center. FHI. Nairobi, FHI 360,.
Evans, M., V. Bergum, et al. (2004). "Relational Ethics and Genetic Counseling." Nursing Ethics **11**(5): 459-471.
Fairhead, J., M. Leach, et al. (2006). "Public engagement with science? Local understandings of a vaccine trial in the Gambia." J Biosoc Sci **38**(1): 103-116.
Fairhead, J., M. Leach, et al. (2006). "Where techno-science meets poverty: medical research and the economy of blood in The Gambia, West Africa." Soc Sci Med **63**(4): 1109-1120.
Fitzgerald, D. W., C. Marotte, et al. (2002). "Comprehension during informed consent in a less-developed country." Lancet **360**(9342): 1301-1302.
Flick, U. (2009). An Introduction to Qualitative Research. London, SAGE Publishers.
Flicker, S., R. Travers, et al. (2007). "Ethical dilemmas in community-based participatory research: recommendations for institutional review boards." J Urban Health **84**(4): 478-493.
Food Security Assessment Team (2008). Kilifi District report: Short Rains Food Security Assessement. Nairobi, Ministry of Agriculture.
Forde, S. (2010). Playing by Their Rules: Coastal teenage girls in Kenya on life, love and football. Kilifi, Moving the Goalposts, Kenya.
Foster, M. W., A. J. Eisenbraun, et al. (1997). "Communal discourse as a supplement to informed consent for genetic research." Nat Genet **17**(3): 277-279.
Fowler, R. A., N. K. Adhikari, et al. (2008). "Clinical review: critical care in the global context--disparities in burden of illness, access, and economics." Crit Care **12**(5): 225.
Friedman, A., E. Robbins, et al. (2012). "Which benefits of research participation count as 'direct'?" Bioethics **26**(2): 60-67.
Fries, J. F. and E. Krishnan (2004). "Equipoise, design bias, and randomized controlled trials: the elusive ethics of new drug development." Arthritis Res Ther **6**(3): R250-255.
Gadow, S. (1999). "Relational narrative: the postmodern turn in nursing ethics." Sch Inq Nurs Pract **13**(1): 57-70.
Geissler, P. W. (2005). "'Kachinja are coming!': Encounters Around Medical Research Work in Kenyan Vilages." Africa **75**(02): 173-202.
Geissler, P. W. (2011). "'Transport to Where?'." Journal of Cultural Economy **4**(1): 45-64.
Geissler, P. W., A. Kelly, et al. (2008). "'He is now like a brother, I can even give him some blood'--relational ethics and material exchanges in a malaria vaccine 'trial community' in The Gambia." Soc Sci Med **67**(5): 696-707.
Geissler, P. W. and C. Molyneux, Eds. (2011). Evidence, Ethos and Experiment: The Anthropology and History of Medical Research in Africa. Oxford, Berghahn Books.

Geissler, P. W. and R. Pool (2006). "Editorial: Popular concerns about medical research projects in sub-Saharan Africa--a critical voice in debates about medical research ethics." Trop Med Int Health **11**(7): 975-982.

Gikonyo, C., P. Bejon, et al. (2008). "Taking social relationships seriously: lessons learned from the informed consent practices of a vaccine trial on the Kenyan Coast." Soc Sci Med **67**(5): 708-720.

Gilson, L. (2003). "Trust and the development of health care as a social institution." Soc Sci Med **56**(7): 1453-1468.

Gilson, L. (2005). "Editorial: building trust and value in health systems in low- and middle-income countries." Soc Sci Med **61**(7): 1381-1384.

Gilson, L. (2006). "Trust in health care: theoretical perspectives and research needs." J Health Organ Manag **20**(5): 359-375.

Gottlieb, B. H. (1985). "Social networks and social support: an overview of research, practice, and policy implications." Health Educ Q **12**(1): 5-22.

Goudge, J. and L. Gilson (2005). "How can trust be investigated? Drawing lessons from past experience." Soc Sci Med **61**(7): 1439-1451.

Graboyes, M. (2010). "Fines, orders, fear . . . and consent? Medical research in East Africa, C. 1950s." Dev World Bioeth **10**(1): 34-41.

Grady, C. (2001). "Money for research participation: does in jeopardize informed consent?" Am J Bioeth **1**(2): 40-44.

Graneheim, U. H. and B. Lundman (2004). "Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness." Nurse Educ Today **24**(2): 105-112.

Grant, R. W. and J. Sugarman (2004). "Ethics in human subjects research: do incentives matter?" J Med Philos **29**(6): 717-738.

Green, J. and N. Thorogood (2007). Qualitative Methods for Health Research, SAGE Publications.

Green, L. W. and S. L. Mercer (2001). "Can public health researchers and agencies reconcile the push from funding bodies and the pull from communities?" Am J Public Health **91**(12): 1926-1929.

Hall, M. A., E. Dugan, et al. (2001). "Trust in physicians and medical institutions: what is it, can it be measured, and does it matter?" Milbank Q **79**(4): 613-639, v.

Health Sector Working Group (2012). Medium Term Expenditure Framework (MTEF) for the Period 2012/13 - 2014/15. Nairobi, Ministry of Health: 67.

Heckathorn, D. D. (1997). "Respondent-Driven Sampling: A New Approach to the Study of Hidden Populations." Social Problems **44**(2): 174-199.

Hedgecoe, A. M. (2004). "Critical bioethics: beyond the social science critique of applied ethics." Bioethics **18**(2): 120-143.

Ho, A. (2008). "Relational autonomy or undue pressure? Family's role in medical decision-making." Scand J Caring Sci **22**(1): 128-135.

Hurst, S. (2010). "What 'Empirical turn in Bioethics'?" Bioethics **24**(8): 439-444.

Huston, P. and M. Rowan (1998). "Qualitative studies. Their role in medical research." Can Fam Physician **44**: 2453-2458.

Hyder, A. A. and M. W. Merritt (2009). "Ancillary care for public health research in developing countries." Jama **302**(4): 429-431.

Ijsselmuiden, C. B., N. E. Kass, et al. (2010). "Evolving values in ethics and global health research." Glob Public Health **5**(2): 154-163.

Ingersoll-Dayton, B. and T. C. Antonucci (1988). "Reciprocal and nonreciprocal social support: contrasting sides of intimate relationships." J Gerontol **43**(3): S65-73.

Ives, J. and M. Dunn (2010). "Who's arguing: A call for Reflexivity in Bioethics." Bioethics **24**(5): 256-265.
Jahn, A., S. Floyd, et al. (2010). "Declining child mortality in northern Malawi despite high rates of infection with HIV." Bull World Health Organ **88**(10): 746-753.
Kaler, A. and S. C. Watkins (2001). "Disobedient Distributors: Street-level Bureaucrats and Would-be Patrons in Community-based Family Planning Programs in Rural Kenya." Studies in Family Planning **32**(3): 254-269.
Kamuya, D., V. Marsh, et al. (2011). "What we learned about voluntariness and consent: incorporating "background situations" and understanding into analyses." Am J Bioeth **11**(8): 31-33.
Kamuya, D. M., V. Marsh, et al. (2013). "Engaging Communities to Strengthen Research Ethics in Low-Income Settings: Selection and Perceptions of Members of a Network of Representatives in Coastal Kenya." Developing World Bioethics **13**(1): 10-20.
Kamuya, D. M., S. J. Theobald, et al. (2013). "Evolving Friendships and Shifting Ethical Dilemmas: Fieldworkers' Experiences in a Short Term Community Based Study in Kenya." Developing World Bioethics **13**(1): 1-9.
Kandiyoti, D. (1988). "Bargaining with Patriarchy." Gender & Society **2**(3): 274-290.
Karamagi, C. A., J. K. Tumwine, et al. (2006). "Intimate partner violence against women in eastern Uganda: implications for HIV prevention." BMC Public Health **6**: 284.
Kass, N. E., A. A. Hyder, et al. (2007). "The structure and function of research ethics committees in Africa: a case study." PLoS Med **4**(1): e3.
Kilama, W. L. (2009). "The 10/90 gap in sub-Saharan Africa: Resolving inequities in health research." Acta Trop.
Kingori, P., M. Muchimba, et al. (2010). "'Rumours' and clinical trials: a retrospective examination of a paediatric malnutrition study in Zambia, southern Africa." BMC Public Health **10**: 556.
KNBS (2005). Geographic Dimensions of Wellbeing in Kenya: Who and Where are the Poor? K. N. B. o. Statistics. Nairobi, Kenya National Bureau of Statistics**:** 80.
KNBS (2006). Kenya Intergrated Intergrated Household Bidget Survey 2005/06. K. N. B. o. Statistics. Nairobi, Kenya National Bureau of Statistics.
KNBS (2010). The 2009 Kenya Population and Housing Census: Population Distribution By Administrative Units. K. N. B. o. Statistics. Nairobi, Kenya National Bureau of Statistics. **1A:** 206.
KNBS (2010). The 2009 Kenya Population and Housing Census: Population Distribution by Political Units K. N. B. o. Statistics. Nairobi, Kenya Nation Bureau of Statistics. **1B:** 297.
KNBS (2010). Kenya Demographic and Health Survey 2008-09. K. N. B. o. Statistics. Nairobi, Kenya National Bureau of Statistics**:** 430.
KNBS. (2012). Kenya Facts and Figures 2012. C. B. o. S. C.-. Kenya. Nairobi, Government of Kenya.
Koen, J., C. Slack, et al. (2008). "Payment of trial participants can be ethically sound: moving past a flat rate." S Afr Med J **98**(12): 926-929.
Kottow, M. H. (2007). "Should research ethics triumph over clinical ethics?" J Eval Clin Pract **13**(4): 695-698.
Krosin, M. T., R. Klitzman, et al. (2006). "Problems in comprehension of informed consent in rural and peri-urban Mali, West Africa." Clin Trials **3**(3): 306-313.

Lairumbi, G. M., P. Michael, et al. (2011). "Ethics in practice: the state of the debate on promoting the social value of global health research in resource poor settings particularly Africa." BMC Med Ethics **12**: 22.

Lairumbi, G. M., S. Molyneux, et al. (2008). "Promoting the social value of research in Kenya: examining the practical aspects of collaborative partnerships using an ethical framework." Soc Sci Med **67**(5): 734-747.

Lairumbi, G. M., M. Parker, et al. (2011). "Stakeholders understanding of the concept of benefit sharing in health research in Kenya: a qualitative study." BMC Med Ethics **12**: 20.

Landy, D. C. and R. R. Sharp (2010). "Examining the potential for exploitation by local intermediaries." Am J Bioeth **10**(3): 12-13.

Langford, C. P., J. Bowsher, et al. (1997). "Social support: a conceptual analysis." J Adv Nurs **25**(1): 95-100.

Larkin, P. J., B. D. de Casterle, et al. (2008). "A relational ethical dialogue with research ethics committees." Nurs Ethics **15**(2): 234-242.

Lavery, J., C. Grady, et al. (2007). Ethical Issues in International Biomedical Research: A casebook., Oxford University Press.

Lavery, J. V., S. V. Bandewar, et al. (2010). "'Relief of oppression': an organizing principle for researchers' obligations to participants in observational studies in the developing world." BMC Public Health **10**: 384.

Lavery, J. V., P. O. Tindana, et al. (2010). "Towards a framework for community engagement in global health research." Trends Parasitol **26**(6): 279-283.

Leach, M. A., J. R. Fairhead, et al. (2008). "New therapeutic landscapes in Africa: parental categories and practices in seeking infant health in the Republic of Guinea." Soc Sci Med **66**(10): 2157-2167.

Lema, V. M., M. Mbondo, et al. (2009). "Informed consent for clinical trials: a review." East Afr Med J **86**(3): 133-142.

Lemmens, T. and C. Elliott (2001). "Justice for the professional guinea pig." Am J Bioeth **1**(2): 51-53.

Lindegger, G., C. Milford, et al. (2006). "Beyond the checklist: assessing understanding for HIV vaccine trial participation in South Africa." J Acquir Immune Defic Syndr **43**(5): 560-566.

Lindegger, G., M. Quayle, et al. (2007). "Local knowledge and experiences of vaccination: implications for HIV-preventive vaccine trials in South Africa." Health Educ Behav **34**(1): 108-123.

Lindegger, G. and L. M. Richter (2000). "HIV vaccine trials: critical issues in informed consent." S Afr J Sci **96**: 313-317.

Long, N. (1999). The Multiple Optic of Interface Analysis (working title). UNESCO Background paper on Interface Analysis**:** 1-24.

Lukes, S. (2005). Power A Radical View; 2nd edition. Hampshire, Palgrave Macmillian.

MacKay, E. and P. O'Neill (1992). "What creates the dilemma in ethical dilemmas? Examples from psychological practice." Ethics Behav **2**(4): 227-244.

Macklin, R. (1989). "The paradoxical case of payment as benefit to research subjects." Irb **11**(6): 1-3.

Macklin, R. (2010). "Fair benefits in developing countries: maximin as a good start." Am J Bioeth **10**(6): 36-37.

MacQueen, K. M., E. McLellan, et al. (2001). "What is community? An evidence-based definition for participatory public health." Am J Public Health **91**(12): 1929-1938.

Malterud, K. (2001). "The art and science of clinical knowledge: evidence beyond measures and numbers." Lancet **358**(9279): 397-400.
Malterud, K. (2001). "Qualitative research: standards, challenges, and guidelines." Lancet **358**(9280): 483-488.
Manafa, O., G. Lindegger, et al. (2007). "Informed consent in an antiretroviral trial in Nigeria." Indian J Med Ethics **4**(1): 26-30.
Mandava, A., C. Pace, et al. (2012). "The quality of informed consent: mapping the landscape. A review of empirical data from developing and developed countries." J Med Ethics.
Marcellus, L. (2005). "The grounded theory method and maternal-infant research and practice." J Obstet Gynecol Neonatal Nurs **34**(3): 349-357.
Marsh, V., D. Kamuya, et al. (2008). "Beginning community engagement at a busy biomedical research programme: experiences from the KEMRI CGMRC-Wellcome Trust Research Programme, Kilifi, Kenya." Soc Sci Med **67**(5): 721-733.
Marsh, V. M., D. K. Kamuya, et al. (2011). "Working with Concepts: The Role of Community in International Collaborative Biomedical Research." Public Health Ethics **4**(1): 26-39.
Marsh, V. M., D. M. Kamuya, et al. (2010). "Experiences with community engagement and informed consent in a genetic cohort study of severe childhood diseases in Kenya." BMC Med Ethics **11**: 13.
Marsh, V. M., D. M. Kamuya, et al. (2011). "'All her children are born that way': gendered experiences of stigma in families affected by sickle cell disorder in rural Kenya." Ethn Health **16**(4-5): 343-359.
Marshall, E. (1986). "Does the moral philosophy of the Belmont Report rest on a mistake?" Irb **8**(6): 5-6.
Marshall, M. N. (1996). "Sampling for qualitative research." Fam Pract **13**(6): 522-525.
Marshall, P. A. (2008). ""Cultural competence" and informed consent in international health research." Camb Q Healthc Ethics **17**(2): 206-215.
Marshall, P. A. and C. Rotimi (2001). "Ethical challenges in community-based research." Am J Med Sci **322**(5): 259-263.
Mays, N. and C. Pope (1995). "Qualitative research: Observational methods in health care settings." Bmj **311**(6998): 182-184.
Mays, N. and C. Pope (1995). "Rigour and qualitative research." Bmj **311**(6997): 109-112.
McKnight, C., D. Des Jarlais, et al. (2006). "Respondent-driven sampling in a study of drug users in New York City: notes from the field." J Urban Health **83**(6 Suppl): i54-59.
McMillan, D. W. and D. M. Chavis (1986). "Sense of Community: A Definitiona and Theory." Journal of community Psychology **14**: 6-21.
Mensch, B. S. and C. B. Lloyd (1998). "Gender differences in the schooling experiences of adolescents in low-income countries: the case of Kenya." Stud Fam Plann **29**(2): 167-184.
Mfutso-Bengo, J., P. Ndebele, et al. (2008). "Why do individuals agree to enrol in clinical trials? A qualitative study of health research participation in Blantyre, Malawi." Malawi Med J **20**(2): 37-41.
Miller, T. and M. Boulton (2007). "Changing constructions of informed consent: qualitative research and complex social worlds." Soc Sci Med **65**(11): 2199-2211.

Mills, E. (2005). "Tenofovir trials raise ethical issues." HIV AIDS Policy Law Rev **10**(2): 31-32.
Minkler, M. (2005). "Community-based research partnerships: challenges and opportunities." J Urban Health **82**(2 Suppl 2): ii3-12.
Mitchell, K., S. Nakamanya, et al. (2002). "Balancing rigour and acceptability: the use of HIV incidence to evaluate a community-based randomised trial in rural Uganda." Soc Sci Med **54**(7): 1081-1091.
Mitchell, K., S. Nakamanya, et al. (2002). "Exploring the community response to a randomized controlled HIV/AIDS intervention trial in rural Uganda." AIDS Educ Prev **14**(3): 207-216.
Molyneux, C., J. Goudge, et al. (2009). "Conducting health related social science research in low income settings: Ethical dilemmas faced in Kenya and South Africa." Journal of International Development **21**: 309-326.
Molyneux, C., B. Hutchison, et al. (2007). "The role of community-based organizations in household ability to pay for health care in Kilifi District, Kenya." Health Policy Plan **22**(6): 381-392.
Molyneux, C. S., G. Murira, et al. (2002). "Intra-household relations and treatment decision-making for childhood illness: a Kenyan case study." J Biosoc Sci **34**(1): 109-131.
Molyneux, C. S., N. Peshu, et al. (2004). "Understanding of informed consent in a low-income setting: three case studies from the Kenyan Coast." Soc Sci Med **59**(12): 2547-2559.
Molyneux, C. S., N. Peshu, et al. (2005). "Trust and informed consent: insights from community members on the Kenyan coast." Soc Sci Med **61**(7): 1463-1473.
Molyneux, C. S., D. R. Wassenaar, et al. (2005). "'Even if they ask you to stand by a tree all day, you will have to do it (laughter)...!': community voices on the notion and practice of informed consent for biomedical research in developing countries." Soc Sci Med **61**(2): 443-454.
Molyneux, S. and P. W. Geissler (2008). "Ethics and the ethnography of medical research in Africa." Soc Sci Med **67**(5): 685-695.
Molyneux, S., C. Gikonyo, et al. (2007). "Incorporating a quiz into informed consent processes: qualitative study of participants' reactions." Malar J **6**: 145.
Molyneux, S., D. Kamuya, et al. (2010). "Community members employed on research projects face crucial, often under-recognized, ethical dilemmas." Am J Bioeth **10**(3): 24-26.
Molyneux, S., S. Mulupi, et al. (2012). "Benefits and payments for research participants: Experiences and views from a research centre on the Kenyan coast." BMC Med Ethics **13**(1): 13.
Mooney, G. and S. Houston (2008). "Equity in health care and institutional trust: a communitarian view." Cadernos de Saúde Pública **24**: 1162-1167.
Morin, S. F., A. Maiorana, et al. (2003). "Community consultation in HIV prevention research: a study of community advisory boards at 6 research sites." J Acquir Immune Defic Syndr **33**(4): 513-520.
Morin, S. F., S. Morfit, et al. (2008). "Building community partnerships: case studies of Community Advisory Boards at research sites in Peru, Zimbabwe, and Thailand." Clin Trials **5**(2): 147-156.
Morris, N. and M. Schneider (2010). "Volunteer research subjects' experience of participation in research on a novel diagnostic technology for breast cancer." Qual Health Res **20**(1): 81-92.

Morrison-Beedy, D., D. Cote-Arsenault, et al. (2001). "Maximizing results with focus groups: moderator and analysis issues." Appl Nurs Res **14**(1): 48-53.

Mosavel, M., R. Ahmed, et al. (2011). "Community researchers conducting health disparities research: Ethical and other insights from fieldwork journaling." Soc Sci Med **73**(1): 145-152.

Mosavel, M., C. Simon, et al. (2005). "Community-based participatory research (CBPR) in South Africa: engaging multiple constituents to shape the research question." Soc Sci Med **61**(12): 2577-2587.

Moser, A., R. Houtepen, et al. (2010). "Realizing autonomy in responsive relationships." Med Health Care Philos **13**(3): 215-223.

Mystakidou, K., I. Panagiotou, et al. (2009). "Ethical and practical challenges in implementing informed consent in HIV/AIDS clinical trials in developing or resource-limited countries." SAHARA J **6**(2): 46-57.

Nakibinge, S., D. Maher, et al. (2009). "Community engagement in health research: two decades of experience from a research project on HIV in rural Uganda." Trop Med Int Health **14**(2): 190-195.

NCAPD (2005). Service Provision Assessment Survey 2004: National Coordinating Agency for Population and Development (NCAPD),. Nairobi, Ministry of Health.

NCST (2005). Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya: National Council of Science and Technology (NCST). Nairobi, Government of Kenya. **NCST No. 45**.

Nelson, R. M., T. Beauchamp, et al. (2011). "The Concept of Voluntary Consent." The American Journal of Bioethics **11**(8): 6-16.

NIMH (2008). "The role of Community Advisory Boards (CABs) in Project Eban." J Acquir Immune Defic Syndr **49 Suppl 1**: S68-74.

Nyandieka, L. N., A. Bowden, et al. (2002). "Managing a household survey: a practical example from the KENQOL survey. Kenya Quality of Life." Health Policy Plan **17**(2): 207-212.

Nyika, A., R. Chilengi, et al. (2010). "Engaging diverse communities participating in clinical trials: case examples from across Africa." Malar J **9**: 86.

Nyika, A., W. Kilama, et al. (2009). "Composition, training needs and independence of ethics review committees across Africa: are the gate-keepers rising to the emerging challenges?" J Med Ethics **35**(3): 189-193.

Nyika, A., W. Kilama, et al. (2009). "Capacity building of ethics review committees across Africa based on the results of a comprehensive needs assessment survey." Dev World Bioeth **9**(3): 149-156.

Olotu, A., J. Lusingu, et al. (2011). "Efficacy of RTS,S/AS01E malaria vaccine and exploratory analysis on anti-circumsporozoite antibody titres and protection in children aged 5-17 months in Kenya and Tanzania: a randomised controlled trial." Lancet Infect Dis **11**(2): 102-109.

ORA (Accessed 2011). Ethics documents. Office of Regulatory Affairs.

Osamor, P. E. and N. Kass (2012). "Decision-making and Motivation to Participate in Bioemdical Research in Southwest Nigeria." Developing World Bioethics **12**(2): 87-95.

Page-Shafer, K., V. Saphonn, et al. (2005). "HIV prevention research in a resource-limited setting: the experience of planning a trial in Cambodia." Lancet **366**(9495): 1499-1503.

Papadopoulos, I. and S. Lees (2002). "Developing culturally competent researchers." J Adv Nurs **37**(3): 258-264.

Parker, M. (2012). Ethical Problems and Genetics Practice. New York, Cambridge University Press, New York.
Parkin, D. J. (1991). From west to east: the works of marriage, Cambridge University Press.
Parkin, D. J. (1991). Sacrod Void: Spatial images of Work and Ritual Among Giriama of kenya. Cambridge, Cambridge University Press.
Participants (2002). " Conference on Ethical Aspects of Research in Developing Countries: Fair benefits for research in developing countries." Science **298**(5601): 2133-2134.
Participants (2004). "Moral standards for research in developing countries: from "reasonable availability" to "fair benefits"." Hastings Cent Rep **34**(3): 17-27.
Participants (2011). Workshop report on Consent and Community Engagment in Health Research - Reviewing and Developing Research and Practice Workshop on Consent and Community Engagment in Health Research: Reviewing and Developing Research and Practice,.
PATH (2003). Guidelines for Implementing Supportive Supervision: A step-by-step guide with tools to support implementation. Seattle**:** 1-72.
Patton, M. Q. (1999). "Enhancing the quality and credibility of qualitative analysis." Health Serv Res **34**(5 Pt 2): 1189-1208.
Patton, M. Q. (2002). Qualitative Research & Evaluation Methods, Sage Publications, Inc.
Phillips, T. (2010). "Protecting the subject: PDR and the potential for compromised consent." Am J Bioeth **10**(3): 14-15.
Phillips, T. (2012). "More on benchmarks of fairness: response to Ballantyne." Bioethics **26**(1): 49-56.
Pierre, J. and B. G. Peters (2003). Handbook of Public Administration. London, SAGE Publications LTD.
Pope, C. and N. Mays (1995). "Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research." Bmj **311**(6996): 42-45.
Potvin, L., M. Cargo, et al. (2003). "Implementing participatory intervention and research in communities: lessons from the Kahnawake Schools Diabetes Prevention Project in Canada." Soc Sci Med **56**(6): 1295-1305.
Prendergast, C. (2007). "The Motivation and Bias of Bureaucrats." The American Economic Review **97**(3): 180-196.
Quinn, S. C. (2004). "Ethics in public health research: protecting human subjects: the role of community advisory boards." Am J Public Health **94**(6): 918-922.
Quinn, S. C., D. Gamble, et al. (2001). "Ethics and community-based education: balancing respect for the community with professional preparation." Fam Community Health **23**(4): 9-23.
Ragin, D. F., E. Ricci, et al. (2008). "Defining the "community" in community consultation for emergency research: findings from the community VOICES study." Soc Sci Med **66**(6): 1379-1392.
Reddy, P., D. Buchanan, et al. (2010). "The role of community advisory boards in health research: Divergent views in the South African experience." SAHARA J **7**(3): 2-8.
Ritchie, J. and J. Lewis (2009). Qualitative Research practice: A guide for social science students and researchers, SAGE Publications.
Rotimi, C., M. Leppert, et al. (2007). "Community engagement and informed consent in the International HapMap project." Community Genet **10**(3): 186-198.

Sanchez, S., G. Salazar, et al. (2001). "Informed consent procedures: responsibilities of researchers in developing countries." Bioethics **15**(5-6): 398-412.
Schuklenk, U. (2010). "For-profit clinical trials in developing countries--those troublesome patient benefits." Am J Bioeth **10**(6): 52-54.
Scott, J. A., E. Bauni, et al. (2012). "Profile: The Kilifi Health and Demographic Surveillance System (KHDSS)." Int J Epidemiol.
Shagi, C., A. Vallely, et al. (2008). "A model for community representation and participation in HIV prevention trials among women who engage in transactional sex in Africa." AIDS Care **20**(9): 1039-1049.
Shimpuku, Y. and K. F. Norr (2012). "Working with interpreters in cross-cultural qualitative research in the context of a developing country: systematic literature review." J Adv Nurs.
Shubis, K., O. Juma, et al. (2009). "Challenges of establishing a Community Advisory Board (CAB) in a low-income, low-resource setting: experiences from Bagamoyo, Tanzania." Health Res Policy Syst **7**: 16.
Simon, C. and M. Mosavel (2010). "Community members as recruiters of human subjects: ethical considerations." Am J Bioeth **10**(3): 3-11.
Simon, C. and M. Mosavel (2010). "Response to open peer commentaries on "Community members as recruiters of human subjects: ethical considerations"." Am J Bioeth **10**(3): W1-3.
Simon, C., M. Mosavel, et al. (2007). "Ethical challenges in the design and conduct of locally relevant international health research." Soc Sci Med **64**(9): 1960-1969.
Sin, C. H. (2005). "Seeking Informed Consent: Reflections on Research Practice." Sociology **39**(2): 277-294.
Smith, W. J. (2001). "Revisiting the Belmont report." Hastings Cent Rep **31**(2): 5.
Sofaer, S. (1999). "Qualitative methods: what are they and why use them?" Health Serv Res **34**(5 Pt 2): 1101-1118.
Standing, H. and A. M. Chowdhury (2008). "Producing effective knowledge agents in a pluralistic environment: what future for community health workers?" Soc Sci Med **66**(10): 2096-2107.
Strauss, R. P., S. Sengupta, et al. (2001). "The role of community advisory boards: involving communities in the informed consent process." Am J Public Health **91**(12): 1938-1943.
Streeton, R., M. Cooke, et al. (2004). "Researching the researchers: using a snowballing technique." Nurse Res **12**(1): 35-46.
Suri, A., K. Gan, et al. (2007). "Voices from the field: perspectives from community health workers on health care delivery in rural KwaZulu-Natal, South Africa." J Infect Dis **196 Suppl 3**: S505-511.
Tangwa, G. B. (2007). "How not to compare Western scientific medicine with African traditional medicine." Dev World Bioeth **7**(1): 41-44.
Tekola, F., S. J. Bull, et al. (2009). "Tailoring consent to context: designing an appropriate consent process for a biomedical study in a low income setting." PLoS Negl Trop Dis **3**(7): e482.
Theobald, S., R. Tolhurst, et al. (2006). "Gender, equity: new approaches for effective management of communicable diseases." Trans R Soc Trop Med Hyg **100**(4): 299-304.
Tiffany, J. S. (2006). "Respondent-driven sampling in participatory research contexts: participant-driven recruitment." J Urban Health **83**(6 Suppl): i113-124.

Tindana, P. O., L. Rozmovits, et al. (2011). "Aligning community engagement with traditional authority structures in global health research: a case study from northern Ghana." Am J Public Health **101**(10): 1857-1867.

Tindana, P. O., J. A. Singh, et al. (2007). "Grand challenges in global health: community engagement in research in developing countries." PLoS Med **4**(9): e273.

Tolhurst, R., Y. P. Amekudzi, et al. (2008). ""He will ask why the child gets sick so often": the gendered dynamics of intra-household bargaining over healthcare for children with fever in the Volta Region of Ghana." Soc Sci Med **66**(5): 1106-1117.

True, G., L. B. Alexander, et al. (2011). "Misbehaviors of front-line research personnel and the integrity of community-based research." J Empir Res Hum Res Ethics **6**(2): 3-12.

Upshur, R. E., J. V. Lavery, et al. (2007). "Taking tissue seriously means taking communities seriously." BMC Med Ethics **8**: 11.

Vallely, A., C. Shagi, et al. (2007). "The benefits of participatory methodologies to develop effective community dialogue in the context of a microbicide trial feasibility study in Mwanza, Tanzania." BMC Public Health **7**: 133.

Wallerstein, N. B. and B. Duran (2006). "Using community-based participatory research to address health disparities." Health Promot Pract **7**(3): 312-323.

Weijer, C. (1999). "Protecting communities in research: philosophical and pragmatic challenges." Camb Q Healthc Ethics **8**(4): 501-513.

Weijer, C., G. Goldsand, et al. (1999). "Protecting communities in research: current guidelines and limits of extrapolation." Nat Genet **23**(3): 275-280.

Weijer, C. and P. B. Miller (2004). "Protecting communities in pharmacogenetic and pharmacogenomic research." Pharmacogenomics J **4**(1): 9-16.

Wendler, D. (2004). "Risk standards for pediatric research: rethinking the Grimes ruling." Kennedy Inst Ethics J **14**(2): 187-198.

Wertheimer, A. and F. G. Miller (2008). "Payment for research participation: a coercive offer?" J Med Ethics **34**(5): 389-392.

White, L. (2000). Speaking with Vampires: Rumour and History in Colonial Africa., University of California Press.

WHO (2002). Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation Geneva, World Health Organization.

WHO (2009). Country Cooperation strategy; at a glance. Geneva, World Health Organization.

Williams, B., L. Irvine, et al. (2007). "When "no" might not quite mean "no"; the importance of informed and meaningful non-consent: results from a survey of individuals refusing participation in a health-related research project." BMC Health Serv Res **7**: 59.

WMA (1979). "Protection of human subjects; Belmont Report: notice of report for public comment." Fed Regist **44**(76): 23191-23197.

Wolcott, H. (2005). The Art of Fieldwork. Oxford, Rowman & Littlefield Publishers, Inc.

Wong, J. C. and M. Bernstein (2011). "Payment of research subjects for more than minimal risk trials is unethical." Am J Med Sci **342**(4): 294-296.

Appendices

Appendix A: Ethical principles and benchmarks for multinational research

(Emanuel, Wendler et al. 2004 p931)

Principles	Benchmarks
Collaborative partnerships	Develop partnerships with researchers, makes of health policies and the community
	Involve partners in sharing responsibilities for determining the importance of heath problem, assessing the value of research, planning, conducting, and overseeing research and integrating research into the health care system
	Respect the community's values, culture, traditions, and social places.
	Develop the capacity for researchers, makers of health policies, and the community to become full and equal partners in the research enterprise
	Ensure that recruited participants and communities receive benefits from the conduct and results of the research
	Share fairly financial and other rewards of the research.
Social value	Specify the beneficiaries – who
	Assess the importance of the health problems being investigated and the prospective value of the research for each of the beneficiaries – what
	Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long-term research collaboration, and/or health system improvements
	Prevent supplanting the extant health system infrastructure and services
Scientific validity	Ensure that the scientific design of the research realizes the social value for the primary beneficiaries of the research
	Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the health care interventions to which they are entitled.
	Ensure that the research study is feasible within the social, political, and cultural context or with sustainable improvements in the local health-care and physical infrastructure.
Fair selection of study	Select the study population to ensure scientific validity of the

population	research
	Select the study population to minimize risks of the research and enhance other principles especially collaborative partnerships and social value
	Identify and protect vulnerable populations
Favourable risk-benefit ratio	Assess the potential risks and benefits of the research to the study population in the context of its health risks
	Assess the risk-benefit by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations.
Independent review	Ensure public accountability through reviews mandated by laws and regulations
	Ensure public accountability through transparency and review by other international and nongovernmental bodies, as appropriate.
	Ensure independence and competence of the reviews.
Informed consent	Involve the community in establishing recruitment procedures and incentives
	Disclose information in culturally and linguistically appropriate formats.
	Implement supplement community and familial consent procedures where culturally appropriate.
	Obtain consent in culturally and linguistically appropriate formats
	Ensure the freedom to refuse or withdraw.
Respect for recruited participants and study communities	Develop and implement procedures to protect the confidentiality of recruited and enrolled participants.
	Ensure that participants know they can withdraw without penalty.
	Provide enrolled participants with information that arises in the course of the research study.
	Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participants, at least as good as existing local norms.
	Inform participants and the study community of the results of the research.

Appendix B: ERC Approval Letter

KENYA MEDICAL RESEARCH INSTITUTE

P.O. Box 54840 - 00200 NAIROBI, Kenya
Tel: (254) (020) 2722541, 2713349, 0722-205901, 0733-400003; Fax: (254) (020) 2720030
E-mail: director@kemri.org info@kemri.org Website:www.kemri.org

DIRECTOR CENTRE FOR GEOGRAPHIC MEDICINE RESEARCH, COAST

KEMRI/RES/7/3/1 **December 16, 2009**

TO: **DR. CATHERINE MOLYNEUX**
(PRINCIPAL INVESTIGATOR)

THROUGH: **DR. NORBERT PESHU,**
THE DIRECTOR, CGMR-C,
KILIFI

forwarded 18/12/09

RE: **SSC PROTOCOL NO. 1463 (*REQUEST FOR 1ST AMENDMENT*): STRENGTHENING COMMUNITY ENGAGEMENT IN HEALTH RESEARCH IN KILIFI THROUGH DOCUMENTING EVALUATING AND AMENDING THE MAIN COMMUNICATION SYSTEMS AND STRUCTURES**

This is to inform you that during the 173rd meeting of KEMRI/National Ethics Review Committee held on Tuesday 8th December 2009, the suggested amendment to the approved study was considered.

The Committee was of the view that the proposed amendment, to add another approach to selecting research participants that includes additional study specific observations, and individual and group interviews with participants, community representatives, fieldworkers and PIs that are closely linked to each case study, does not alter the risk/benefit status of the study and is **granted approval** for implementation.

You are required to submit any further amendments to this protocol and other information pertinent to human participation in this study to the SSC and ERC for review prior to initiation.

Yours sincerely,

R.C.Kithinji

R. C. KITHINJI,
FOR: SECRETARY,
KEMRI/NATIONAL ETHICS REVIEW COMMITTEE

KEMRI/WELLCOME TRUST RESEARCH PROGRAMME
18 DEC 2009
RECEIVED
P. O. Box 230-80108 KILIFI

Appendix C: Informed consent forms

C0NSENT FORM: FGD WITH CASE STUDY PARTICIPANTS

Study Title: *Field worker and research participant interactions: implications for community engagement processes in developing countries:*

Institution	Individuals
KEMRI CGMRC/Wellcome Trust research programme, Kilifi	**Dorcas Kamuya, Dr. Catherine Molyneux, Dr. Vicki Marsh, and** *(names of PIs of community based studies)*
Liverpool School of Tropical Medicine	**Dr. Sally Theobald**
London School of Hygiene and Tropical Medicine	**Dr. Wenzel Geissler**

What is KEMRI?
KEMRI is a government organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit. All research at KEMRI has to be approved before it begins by committees in Kilifi, a national scientific committee and an independent national ethical review committee. These committees make sure that every research is important, and that participants' safety and rights are respected.

What is this research about and what does it involve?
KEMRI is conducting a study is to find out what people think about how we engage with research participants. We hope to talk to about 30 people who have been involved in KEMRI research recently. We will talk to those people either individually or in groups.

You have been invited to participate because we feel that your experience as a community member can contribute much to our understanding of peoples' views of KEMRI. We will ask questions about KEMRI and its working and about the study you are participating [RTSS study]. You do not need to discuss any information you are not comfortable in sharing. There are no right and wrong answers, and we encourage everyone to express themselves freely throughout the discussion. Only the people involved in the discussion, the person asking the questions, and a note-taker will be present. The discussion will be tape-recorded to assist later in fully writing up the information. No-one will be identified by name in notes or on the tape. We will, however, record your age and years of education.

Are there any disadvantages or advantages involved in taking part?
The discussions should take approximately two hours. There are no individual benefits to taking part, but in participating in this discussion you will help us to understand more about how KEMRI interacts with research participants and community members.

Who will have access to the information I give?

We will not share individual information about you or other participants with anyone beyond a few people who are closely concerned with the research.

To ensure confidentiality we will not use participants' names in our recording today or in reports in the future, and instead use numbers to identify participants. All of our documents/tapes are stored securely in locked cabinets and on password protected computers. The tapes will be destroyed after completion of the research. We will ask everybody in the discussion to keep what is said in the group confidential, but it is important to recognize that we cannot stop participants sharing what they have heard. The knowledge gained from this research will be shared in summary form, without revealing individuals' identities, with community representatives and leaders, KEMRI and KDH staff, and with other researchers working on community engagement in medical research.

What will happen if I refuse to participate?
All participation in research is voluntary. You are free to decide if you want to take part or not. If you do agree you can change your mind at any time without any consequences.

What if I have any questions?
You are free to ask me any question about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

PI's name(s) and contacts
Dorcas Kamuya
KEMRI- Wellcome Trust , Kilifi
P.O.Box. 230, Kenya. Telephone: 0722-236080 or 041 7522 063

If you want to ask someone independent anything about this research please contact
Dr. Sam Kinyanjui, at KEMRI – Wellcome Trust
P.O.Box 230, Kilifi. Telephone: 041-522 063
Or
The Secretary - KEMRI/National Ethics Review Committee
P. O. BOX 54840-00200, Nairobi, Tel number: 020 272 2541 Mobile: 0722205901 or 0733400003

CONSENT FORM (FGDs interviews)

Study Title: *Field worker and research participant interactions: implications for community engagement processes in developing countries:*

Ask the group to identify two participants, one who can sign (the representative) and one who can witness this form on behalf of all members as below.

Representative statement:
I agree that:
All members of this group have had the study explained to them, have understood all that has been said or read, have all their questions answered satisfactorily, and understand that they may change their minds at any stage without any future consequences.
All members of the group agree to participant in the discussion □ Yes
All members of the group agree for the discussion to be tape-recorded □ Yes

Signature of representative: _____ Date: _____

Representative's Name: _____
(please print name)

Witness statement:
I certify that
All members of this group have had the study explained to them, have understood all that has been said or read, have had all questions answered satisfactorily, and understand that they may change their minds at any stage without consequences.

All members of the group agree to participant in the discussion □ Yes
All members of the group agree for the discussion to be tape-recorded □ Yes.

Signature of witness: _____ **Date** _____

Witness's name _____
(please print name)

ALL PARTICIPANTS SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP

Appendix D: Checklist and topic discussion guide with Community Liaison Group staff

1. Exploring meaning of "field worker"
   What is your understanding of the term field worker as applied here at KEMRI? (probe)
   - What does the term FW mean? What are the main categories of FWs? Do you have your own way of categorising them, which are these categories?
   - In what ways do FWs differ across categories?
   - How do FWs move across the different categories? And what implications do the movements on the FWs, the studies and KEMRI-WT have?

2. What are community based studies? Can you give some examples of different types? What makes them different?
   a) what are the roles of FWs across different stages of community-based studies.
   b) What is the nature of their interactions, with participants, what factors contribute to this?

   For each stage of community-based studies (refer to examples above), probe;
   - What are the roles for FWs
   - What are challenges do FWs face in implementing their roles?
   - How do FWs cope/resolve these challenges?
   - What approaches do FWs use to ensure they perform their roles well?

3. What are the attributes and characteristic of a FW who is considered to be a good FW?
   - **According to:** a) the immediate supervisor, b) other fieldworkers, c) community (probe for others?).
   - What factors influence whether or not a FW is good? (e.g., personality, dedication, length of service, exposure to different studies, training, supervision, location on is based, skills)

4. From our discussion so far (and from my own previous experience) it seems that there are some particular challenges FWs face, or particularly complex situations they encounter, how do they handle these: Probe for:
   - **Recruitment:** When PIs want higher recruitment rates for studies, or to minimise refusals/withdrawals
   - **Benefits**: When community members feel that the study benefits are inadequate, or are not enough
   - **Inclusion**: When people who did not fit the inclusion criteria want to join a study.
   - **FW understanding of the study**: When FWs find it difficult to understand the study, or the consent form is too complex

5. How do differences in coping change with e.g. length of service, age, seniority, gender of FW?
6. In recent years, there has been a change in the ways FWs are employed at the research centre, with emphasis on active advertisement and employment from within the community here. According to you, how is this working?
7. Any recommendations?

Thank the participants for their time

Appendix E: Checklist for FGD with FWs and SFWs

Date of Discussion /__/__/20_	Moderator
Venue:	Note-taker
Time start:	No. of participants at start:
Time stop:	No. of participants at start:
Type of participants	Case study/department

FGD: DEMOGRAPHIC DATA CAPTURE SHEET

Participant number (tag)	Gender	age	Education level	Role in the study/KEMRI	Duration of working in KEMRI	Previous experience/ other qualification

Checklist/Questions:

Establishing the role of FWs in the study

1. You have been in this study for several months, what activities are currently going on in the study?
2. What are your current roles? Have your roles changed in the course of the study, if yes, in what way? (*Prompt*: for involvement at community engagement, information giving and consenting, recruitment, follow-ups).

3. How did you feel when you were offered the opportunity to work in KEMRI? Have these feeling changed? If yes in what way and why?

Facilitating factor/what is working well and challenges FWs face in the field

4. From discussions and my field visits with you, there are some things that are working very well, what are these? (Probe being known in the community, relationship with participants, observing social norms etc).

5. There are also challenges that you face or you may have found yourself in complex situations/complicated situations, what are some of these challenges,

   What did you do/how did you handle the challenges?

6. Generally, how do FWs ensure that participants are retained in the study/continued participating in the study
   Prompt for:

   a. At recruitment and consenting: information in ICF, difficult sections and how handled , consenting process, eligibility criteria (inclusion and exclusion etc), similarities and differences between the 5-17 months group and the 6-12 weeks groups, viz process of information giving and consenting, challenges etc
   b. Follow-up on the following issues and what FWs did when they encountered them
      i. Reasons for "potential participants "to refuse study participation.
      ii. decision making on continued study participation
      iii. withdrawals – numbers and reasons
      iv. Silent refusals (SR)- whether they encounter silent refusals (SR), how they know it was a SR, why people/participants use SR instead of outright refusal.
      v. Where couples differed on continued study participation and how handled (include where participants temporary out-migrate)
   c. Logistical challenges e.g. distances to inaccessible areas,
   d. Study benefits to participants: what benefits are given, any additional benefits requested and how they handle such requests
   e. How they ensure they meet the weekly targets.
7. On reflections, what was the most challenging situation you faced in this study? How was it handled? What was your role in resolving it? What are your opinions about the way it was resolved?

Support system:

There are quite a number of positive things that you are doing and a number of challenges you face as we have discussed. We have also looked at how these challenges are resolved. In the next few minutes, I would like us to discuss a little bit about the support that is available to you, both from the study and amongst yourselves.

8. How are you supported to do your roles
   - Logistical support (e.g. bicycles, office space, provision of writing materials, etc).
   - Training and refreshers (updated on new information etc).
   - Meetings (probe for; raising and addressing issues in meeting, adequacy of responses, timeliness, other forums where fws raise and discuss issues – i.e. peer support, support from SFW, PI and Project coordinator)
   - Systems for resolving issues – what mechanisms are used, what Fws feel about adequacy of such mechanisms, timeliness's
   - Any recommendations around the support system provided?
   - Overall what views do you have on your skills (technical and competence) in handling issues in the field?

Relationship with study participants

9. (*if not already discussed)* There are quite substantial benefits for participants in the study (mention: free health care at the local dispensary and KDH for all ailments, are there other benefits? How do participants feel about these benefits, what do they perceive they are getting the benefits for, what do non-participant say about these benefits?
10. Whom do you think stands for benefit from this study (short term and long term), in what way?
11. You have now been working for KEMRI for nearly a year, are there changes in the way people view you now (e.g. friends, peers, relatives, neighbours, community members etc)? What do community members expect of you?
12. How would you say the relationship between the FWs (study team) and the following groups is, why is it that way a) study participants b) non study community members
13. How is the relationship between community members/households who participating and those not participating in the study? Why do you say that? What the implications of this relationship on the study?

Any recommendations/ideas/opinions around the way field workers in community based studies work.

Thank you for your opinions and your time.

Appendix F: Checklist for interviews with HH in case study A

1. When did you join the study (study name)? How did you know about the study?

2. Since the study involved the whole family/a child, how did you make the decision to participate?
   - prompt for communication within the family, who was involved in making the decision and why; who was not involved and why;
   - what processes were followed to make the decision
   - what issues were considered, which of those mattered the most
   - did some of the people in the family disagree with some of the decisions? What caused this? How did you handle it?
   - For CSA: How did you deal with some households members who wanted to drop out of the study? What were the reasons for wanting to drop out?

3. How long did you participate in the study (a short while then dropped, continued to end of study etc);
   - What made you participate to the end of the study/what made you drop out of the study?
   - What did other HH members feel about this decision?
   - What was done one about the decision (e.g. accepted by the study team, talked out of decision etc)

4. What were some of the difficulties you faced while participating in the study
   (Prompt for study procedures; study team related issues specially FWs; handling non-participants,

   Decisions around continued participation e.g. time involvement, school going children etc;)

5. How do you handle these challenges/overcome?
   (Prompt for consultations with other HH members, FWs/study team involvement in resolution).

6. What views do you have in regards to FWs and the study team (i.e. how did they handle any of the questions and challenges that participants faced etc)

7. What are your views/opinions about the study so far? How do you feel having participated for this period, any regrets?

8. Any recommendations for the FWs, study team, KEMRI?

Appendix G: Checklist/questions for case study B participants

General questions/building rapport

You all have a child/children participating in the malaria vaccine trial (RTSS) study,

- Where did you hear about this study?
- What is this study about?

Decision making on study participation

Since the study involves young children and infants: How were decisions made to involve the child in the study?

i) Who had to be consulted/informed by the study team/FWs a) **at communal level** b) **at family level**:
   - **Who else** was often consulted and why (e.g. child's grand mum, for emancipated minors who else was consulted etc)?
   - Who **often** made the **final decision** for the child's participation, and why? Was this the same/different for the 6-12 weeks and the 5-17 months group?

ii) In making decisions about a child's participation in the study, what did you consider?
   - Study procedure-related e.g. procedures, benefits, previous experiences,
   - Involvement in the research e.g. monthly visits to the dispensary, children getting two vaccines a the same time, children of 6-12 weeks involved in a trial
   - Dealing with non-participants

iii) What role/contribution did the FWs make in facilitating/hindering decision making
   - (**probe** for (and lack of): FW conduct, observing social norms, making efforts to talk to both parents
   - continuous information giving, answering/clarifying issues,
   - Organising transport and clinical visits

iv) In this community, what generally happens when adults do not agree on a decision about a child's participation in a study? What might be the reasons for differences, how are the differences resolved? Who would have the final word in most cases and why? Any exceptions?
   - How does this process differ for a trial compared to for health care?
   - Was the way decisions made for the child's participation in the study different from other decisions about the child (e.g. health care?), if Yes, in what way?

Continued participation:

- Almost all children who joined the study are still in the study, what are some of the reasons for continued participation?
- A few parents withdrew their children from the study, what might have been the reasons that contributed to this?

Silent refusals

- Do you think it is likely that some parents may have wanted to have their children in the study and did not? What may have contributed to this?
- Do you think it is likely that some parents may have wanted to withdraw their children and did not inform the study team/FWs?
    - Why do you think they did not want to inform the study team?
    - What are the ways in which the FWs could have known that parents wanted to withdraw/refuse to participate?
    - Why would the parents not want to out rightly inform the FW of their decision to withdrawal/refuse?
    - What should the FWs/study team do in such instances?
- Overall, whom do you think will benefit from this study? And in what way?

Views on FWs

a) Do you know that KEMRI has employed people from the local community to work on this study? How did they select people? What is their role?
b) What are your views about this approach of employing people from the community to work within the community
c) KEMRI also employs FWs who are based in Kilifi, but who work across the area where most of KEMRI's work is, what do you think are the pros and cons of involving such FWs in a study like this one?
d) What are some of the attributes of FWs that are desirable to the community members

Future participation in KEMRI research:
In future if invited to participate in a KEMRI research, would you participate, why/why not? What would you consider in making that decision?

Recommendations

Appendix H: Observation guide used in case study B

1. General information

Name (short) of study	
Date of visit	FW name/initials
Location	Villages
Schedule FW activities for the day	Name of HH visited that day
Total no. of HH visited	No. of HH missed
Approximate time taken per HH	

2. Observation areas/guide:

1. **At arrival** (e.g. greetings, introductions, welcome,)
   - Information giving about the visit.
   - Questions asked and how response (and who asked those questions), comment on general satisfaction or lack of, of the response given.
   - Participants in or not in, if not in reasons given, appointments made and communicated
2. **Context of household**:
   - Indicators for SES e.g. Type of houses e.g. mud walled, black walled, makuti thatched, firm or falling
3. **Study procedures**:
   - Number of participants from that HH in the study, (number, ages, sex etc).
   - What procedures
   - Where procedures are conducted e.g. outside the house, inside, aside from other HH members etc.
   - Does the FW have the necessary equipment, any ways they are improvising and why?
   - questions asked, and how responded.

4. **Study information giving**
   - Any information given about the study during follow-up visits
   - Questions asked and how responded

5. **General views** in FW work load – e.g. how many HH visited, how long the visits took, any logistical challenges?.
6. **Observer position**:

e.g. how explained my presence to FW, to participant, how received, questions asked, contributions to/participation in the study e.g. assisted in filling forms and why.

7. General comments about the observation

Appendix I: Training programme for enumerators

(NB: used the same enumerators who conducted the 2005 baseline survey)

Objectives

1. To familiarise the enumerators with the questionnaire and with the consent process
2. To plan for logistic for the actual survey.

Time	Activity
9.00am	Introduction, why the survey
8.45	Tracing the households in the maps, locating and filling HHH and EZ numbers in Qn.
9am	Introduce the survey tool (introduction and section 1)– discuss how the questionnaire was conducted at baseline, the sections that were difficult and how they were handled. Discuss and harmonise the translation into Kiswahili and Giriama
10.30am	Break
11am	Section 2 - 4- – go through the questions, discuss issues (see above)
12 noon	Section 5 and 6
1pm	Lunch
2pm	Practise filling the questionnaire and resolve any differences – **two groups of three people each**
4.00pm	Clarifying any issues, discuss the piloting activity for the next day, agree on logistics **Tea break.**
Day 2-3	Piloting of the survey: • Tracing household from map • Introduction at HH • Informed consent • Administer the questionnaire • Answer any questions asked • Exit HH • Debrief at the end o the day

Appendix J: Household survey, relevant section to this research

KEMRI/WELLCOME TRUST CGMRC EVALUATION OF KNOWLEDGE AND ATTITUDES CONCERNING KEMRI'S ROLE AND HEALTH RESEARCH

To be administered to the household head (HHH) or male or eldest female member over 18 years of age or is a parent (for those under 18) if the HH head is not present at the time: Only HH members to respond.

ID01 ID02 ID03 ID04	**1. IDENTIFICATION** EZ number and Household number _____[__][__][__] [__][__][__] Study No. _____ Household head's name (three names) _____ Respondent's Name (**optional**)_____
ID05 ID06	**2. INTERVIEWER VISITS** A Visit 1 B Visit 2 C Visit 3 DATE _____ _____ _____ Interviewer Name _____
ID07 ID08 ID09 ID10	**3. HOUSEHOLD SELECTION STATUS** Originally selected household ----------1 (SKIP TO ID10) Replacement ----------2 (If a replacement) REASON FOR REPLACEMENT Not at home after repeated visits----------1 No eligible respondent----------2 Refused (reason)-- ----------3 Household does not exist..... Other (Specify)----------4 INTERVIEW STATUS Completed interview----------1 Partially completed interview----------2

I have followed the study instructions in explaining this study and the participant consents to participate. S/he has been given opportunity to ask questions which I have answered to the best of my ability. *Signature* .....

START TIME: _____:_____ **END TIME:** _____:_____

Checked by: _____ **Date checked:** _____

Entered by: _____ **Date entered:** _____

FW_____	***Comments on interview quality:***

SECTION 1: BACKGROUND CHARACTERISTICS (double check of census data)

Q1. Sex of respondent 1. Male 2. Female

Q2. Relationship with head of HH
1. HHH 2. Spouse 3. HHH is father (in-law) 4. HHH is mother (in-law) 5. Sibling to HHH 6. Other (specify) _____

Q3. In what month and year were you born? Month _____
Year _____

Q4. How old are you now? Age in complete years _____

Q5. What tribe do you belong to?
1. Giriama
2. Chonyi
3. Digo
4. Kauma
5. Rabai
6. Jibana
7. Kambe
8. Duruma
9. Ribe
10. Other (Specify) _____

SECTION 2: UNDERSTANDING AND VIEWS OF KEMRI'S WORK

Now we would like to find out what information currently exists in the community about KEMRI

Q6. Before our visit today, had you ever heard of KEMRI? 1. Yes 2. No → **Q19**

Q7. From your knowledge or experience, what is KEMRI's role? (JUKUMU) (Multiple responses possible; probe: "Anything else?"; "For what reason do they do this?"; "What do you mean by that?" **AND (if they mention any benefits):** What is the reason that KEMRI gives out such benefits? Who gets these benefits?)

.....
.....
.....
.....

☐ Treating children who are sick at the time of their illness [__]
☐ Learning about diseases - for sake of *all people* with similar problems in the *future* [__]
☐ Assisting the community in other ways (msaada, health care etc) [__]
☐ Providing good health services for people who are attending Kilifi District hospital [__]
☐ Teaching local community about health-related issues [__]
☐ Don't know [__]
☐ Other (specify) _____ [__]

Q8a. Is part of KEMRI's role to assist people beyond Kilifi **District**?
1. Yes 2. No 88. Don't know → **Q9**

Q8b. Please explain what you mean? (If yes, how are others assisted?)

.....
.....
.....
.....

☐ Health policies are changed [__]
☐ Learning about diseases - for sake of *all people* with similar problems in the *future* [__]
☐ Don't know [__]
☐ Other (specify) _____ [__]

Q9. In your opinion, which of these ROLES mentioned above is the most important and why? (*Remind roles mention in Q7 and Q8b)*

.....
.....

QN 10-15 OMITTED[78]

Q16. What do you think KEMRI does with the blood samples it collects? (Probe: "Anything else?" 'For what reason do they do that?' .....
.....
.....

☐ Makes decisions on the treatment of an individual patient [__]
☐ Uses it to learn more about health and illness - *for the sake of all* not individ [__]
☐ Stores it to learn more about health and illness *in the future* - *for the sake of all* [__]
☐ Sells the blood [__]
☐ Pools the blood for transfusions [__]
☐ Don't know [__]
☐ Other (specify) _____ [__]

SECTION 3: RECENT EXPOSURE TO COMMUNICATION ACTIVITIES _ OMITTED

SECTION 4: PLANNING FOR FUTURE COMMUNICATION ACTIVITIES

In the past few years, we have been increasing the amount of information about KEMRI that reaches household members over the next year. Your answers to the following questions about you will assist us consider the best ways to continue to do this in rural and urban Kilifi (e.g. written material, visuals etc.)

Q19. What level of education have you attained? Level reached _____ [__]

Q25a. What is your religious denomination?

1.. Muslim
2. Catholic
3. SDA
4. New Apostolic
5. Salvation Army
6. Jehovah's Witness
7. Pentecostal
8. Presbyterian
9. Anglican
10. Traditionalists
11. Other (specify) _____
99. None

Q25B. – 29 OMITTED

Q30. We have heard many different responses from people about KEMRI, some people are worried about KEMRI and some are supportive. Overall, which of these summarizes your feelings about KEMRI's work in Kilifi?

☐ Strongly supportive ☐ Supportive ☐ Indifferent ☐ Unsupportive ☐ Strongly unsupportive

What makes you say this?
.....
.....
.....

SECTION 5: QUESTIONS ABOUT KCR – OMITTED

SECTION 6: ABOUT FIELDWORKERS AND HEALTH WORKERS

[78] Questions that were not relevant for this research are not included.

In the next few question, I would like to ask you some questions on how KEMRI staff interacts with you

(NB: In case any other respondent is called in to assist in this section, please note the details of the respondent e.g. gender, relationship to HHH/respondent. Also note questions this other respondent answers).

Q33a. Has any KEMRI staff come to visit you in your home in the last **six months** *(mention last month e.g. from September to today)*?

1. Yes **2. NO** **3. Don't Know →34a**

b. How many times have you been visited by a KEMRI staff member over the last **six months**?
.....

c. How many fieldworkers have visited over the last **six months**? .....
.....
.....

d. What did the visits from KEMRI staff include over the last **six** months? (*multiple responses*)
.....
.....

☐ Census – getting information about people in the household [__]
☐ Getting treatment, [__]
☐ Being informed about KEMRI work, [__]
☐ Being requested to join a study, [__]
☐ Collecting information/filling some forms/being asked some questions. [__]
☐ Follow-up of on-going study [__]
☐ Collecting samples (nasal, blood, sample etc), [__]
☐ Other
(specify)_____

QUESTIONS 34-36 OMITTED

SECTION 7: FEELINGS ABOUT KEMRI STAFF AND INSTITUTION

As I had earlier introduced myself to you, am from KEMRI, and we are interested in building the relationship between KEMRI and the community. In this last part, I will therefore ask *your opinions or feelings towards KEMRI and its staff. The way I will ask these questions is slightly different, I will read out a few statements and each time, I would like you to tell me whether you:*

Agree, are **Neutral (that is you neither agree nor disagree) or Disagree.**
These questions are simply seeking your general views or opinions.

Wakubali, **Uko katikati,** **Hukubali,** *Q 37* ***Agree (A), Neutral (N), Disagree (D)***	*A*	*N*	*D*
a. KEMRI fieldworkers who visit homes always try to explain their work to households clearly	A	N	D
b. Your home is visited too often by KEMRI fieldworkers)	A	N	D
c. KEMRI fieldworkers are always truthful in the way they give information and answer questions. (*Wafanyikazi wa KEMRI wa nyanjani huwa niwakweli kila mara wanapopeana ujumbe na wanapojibu maswali*).	A	N	D
d. Overall, KEMRI fieldworkers who visit homes are good at what they do.	A	N	D

EXTRA INFORMATION SECTION: OMITTED

Appendix K: Coding sheet (relevant sections)

Qu	*Name*	*Codes*	
	EZHHnm		N[__][__][__] [__][__][__]
ID03	HHnm	Three names	C - 30
ID05	Visits	1/2/3…	N[__]
ID06	FW	Initials	C[__][__]
ID07	Orig HH	Y/N	C[__]
ID10	Complete	Y/N	C[__]
X2	NResps	1/2/3… includes someone who works in **KEM**RI, has **Rel**ative working in KEMRI, or works in **KDH;** . is/was/relative of **KCR**	N[__]- C[_(3)_]
X3	FW Com	Any important source of concern in FWs comments? (Y/N/DK): FWs feels respondent not giving accurate info or interview could not be completed	C[__][__]
	Silentr	Only if some source of concern…Comments etc suggest a silent refusal and responses to be ignored? Y/N/DK.....	C[__][__]
		SECTION 1	
Q1.	Sex	1. Male 2. Female	N[__]
Q2	HHH	1. HHH 2. Spouse 3. HHH is father (in-law) 4. HHH is mother (in-law) 5. Sibling to HHH 6. Other	N[__]
Q3.	YOB	Year of birth only	N[__][__]
Q4	Age	Assume born 31st June of year of birth if do not have month	N[__][__]
Q5	Tribe	As in questionnaire	N[__][__]
		SECTION 2	
Q6	Heard	1. **Y**es 2. **N**o	C[__]
Q7	7treats	Treating people at the time of illness/provides good health services/distributes drugs – treating for free	[__] (all C)
	7learns	Learning about diseases - for sake of *all people* in the *future*	[__]
	7drugs	Yes - **T**ests new drugs/ trials or **M**akes new drugs (T/M)	[__]-[__]
	7exp	Learns by experience… through practice gets to assist others	[__]
	7aid	Assisting the community (msaada, bus fare, food, nets etc)	[__]
	7teach	Teaching local community about health-related issues	[__]
	7dk	Don't know	[__]
	7other	Other (specify)	[__]
	7spec	*Code for other: a) collects info (not census); DK why; b) teaching - other; c)? 7learns; unclear; d) ?7drugs; unclear; e)?7exp; unclear; f) VCT/HIV testing; g) counting people, sounds like census; h) employment; i) further education i.e. higher learning for staff; j) wants to prevent/ eradicate malaria/diseases; k) trapping mosquitoes l) Collects samples (nasals, blood etc); m)difficult to code n) assists to educates children in schools.*	[__][__][__][__]
Q8a	Elsewhere	1. **Y**es 2. **N**o 88. **D**on't **K**now → **Q9**	C[__][__]
Q8b	8policy	Health policies are changed	[__] (all C)
	8learns	Learning about diseases - for sake of *all people* in the *future*	[__]
	8treats	Treat people/provide services in other places	[__]
	8aid	Assisting others (msaada, bus fare, food, nets etc)	[__]
	8DK	Don't know	[__]
	8Other	Other (specify)	[__]
	8spec	*Code for other: a) not asked/clear HOW; b) Has buildings/HQs/ found elsewhere; c) treats anyone who's sick/assists anyone; d) has heard from people; e) only talks about Kilifi; f) No response; g) For people to attain higher degrees; h) Many people go to KEMRI even from outside Kilifi; i) told by KEMRI staff members; j) seen them in other places; k) started elsewhere then came to Kilifi l) counting people/census*	[__][__][__][__]

Q9	9treats	Treating people at the time of illness/provides good health services/distributes drugs	[__](all C)
	9learns	Learning about diseases - for sake of *all people* in the *future*	[__]
	9drugs	**T**ests new drugs/ trials or **M**akes new drugs (T/M)	[__]
	9exp	Learns by experience… through practice gets to assist others	[__]
	9aid	Assisting the community (msaada, bus fare, food, nets etc bee hives)	[__]
	9teach	Teaching local community about health-related issues……	[__]
	9dk	Don't know/cannot rank /not ranked ……	[__]
	9other	Other (specify) ……	[__]
	9spec	*Code for other: a) collects info; DK why; b) teaching - other; c)? 9learns; unclear; d) ?9drugs; unclear; e)?9exp; unclear ; f) not clear if treats or aid; g) employment; h) HIV test/VCT; i) Census; j) Not clear; k) wants to prevent/eradicate malaria/diseases;*	[__][__][__][__]
QUESTION 10 – 15 OMITTED			
Q16	16treats	Makes decisions on the treatment of an individual patient ……..	[__](all C)
	16learns	Uses to learn about health and illness - *for the sake of all* not individ	[__]
	16exp	Learning by experience ……	[__]
	16stores	Stores to learn about health and illness *in the future - for the sake of all*	[__]
	16sells	Sells the blood ……	[__]
	16pools	Pools the blood for transfusions / **P**ositive (donation/help) / **S**ale	[__]-[__]
	16dk	Don't know……	[__]
	16other	Other (specify) ……	[__]
	16spec	Code for other: *a) those found positive/with probs get aid; b) not clear (?if research); c) stores blood, DK why*	[__][__][__][__]
Q 17-18 – OMITTED			
		SECTION 4	
Q19	Edn	Level reached: Standard, Form, Tertiary, Adult education - yys (99 missing; 88 dk; 00 none)	N[__][__]
Q 20 – 29 OMITTED			
Q30	support	1 Strongly supportive 2 Supportive 3 Indifferent 4 Unsupportive 5 Strongly unsupportive	N[__]
SECTION 5 OMITTED			
		SECTION 6	
Q33a	33fwhome	1. Yes 2. No 88. Don't know ➔ **Q34a**	C[__][__]
Q33b	33fwvisit	Number of times fws visited in six months	N[__][__]
Q33c	33fwnos	Number of fws	N[__][__]
Q33d	33fwinfo	Collect info about family members/census	[__] (all Cs)
	33fwf-up	Followed-up for treatment/check health of child/follow-up in study	[__]
	33consent	Being asked to join study, consenting, ……	[__]
	33samples	Collecting samples/blood/nasal……	[__]
	33dk	……	[__][__]
	33other	Don't Know……	[__]
	33specify	Other (specify)……	[__][__][__][__]
		Specify a) collect information on resources/water sources/sanitation b) seeking directions to another place/home etc; c) collect information about studies/HIV etc.	
QN 34- 36 OMITTED			
		SECTION 7	
37a	37fwinfo	Agree (A), Neutral (N) Disagree (D)	C[__]
37b	37zaidi	Agree (A), Neutral (N) Disagree (D)	C[__]
37c	37fwtrue	Agree (A), Neutral (N) Disagree (D)	C[__]
37d	37fwgen	Agree (A), Neutral (N) Disagree (D)	C[__]
37e	37drcare	Agree (A), Neutral (N) Disagree (D)	C[__]
37f	37drdecn	Agree (A), Neutral (N) Disagree (D)	C[__]
37g	37drward	Agree (A), Neutral (N) Disagree (D)	C[__]

Appendix K: Coding sheet (relevant sections)

Qu	*Name*	*Codes*	
	EZHHnm		N[__][__][__] [__][__][__]
ID03	HHnm	Three names	C - 30
ID05	Visits	1/2/3…	N[__]
ID06	FW	Initials	C[__][__]
ID07	Orig HH	Y/N	C[__]
ID10	Complete	Y/N	C[__]
X2	NResps	1/2/3… includes someone who works in **KEM**RI, has **Rel**ative working in KEMRI, or works in **KDH;** . is/was/relative of **KCR**	N[__]- C[_(3)_]
X3	FW Com	Any important source of concern in FWs comments? (Y/N/DK): FWs feels respondent not giving accurate info or interview could not be completed	C[__][__]
	Silentr	Only if some source of concern…Comments etc suggest a silent refusal and responses to be ignored? Y/N/DK.....	C[__][__]
		SECTION 1	
Q1.	Sex	1. Male 2. Female	N[__]
Q2	HHH	1. HHH 2. Spouse 3. HHH is father (in-law) 4. HHH is mother (in-law) 5. Sibling to HHH 6. Other	N[__]
Q3.	YOB	Year of birth only	N[__][__]
Q4	Age	Assume born 31st June of year of birth if do not have month	N[__][__]
Q5	Tribe	As in questionnaire	N[__][__]
		SECTION 2	
Q6	Heard	1. Yes 2. No	C[__]
Q7	7treats	Treating people at the time of illness/provides good health services/distributes drugs – treating for free	[__] (all C)
	7learns	Learning about diseases - for sake of *all people* in the *future*	[__]
	7drugs	Yes - **T**ests new drugs/ trials or **M**akes new drugs (T/M)	[__]-[__]
	7exp	Learns by experience… through practice gets to assist others	[__]
	7aid	Assisting the community (msaada, bus fare, food, nets etc)	[__]
	7teach	Teaching local community about health-related issues	[__]
	7dk	Don't know	[__]
	7other	Other (specify)	[__]
	7spec	*Code for other: a) collects info (not census); DK why; b) teaching - other; c)? 7learns; unclear; d) ?7drugs; unclear; e)?7exp; unclear; f) VCT/HIV testing; g) counting people, sounds like census; h) employment; i) further education i.e. higher learning for staff; j) wants to prevent/ eradicate malaria/diseases; k) trapping mosquitoes l) Collects samples (nasals, blood etc); m)difficult to code n) assists to educates children in schools.*	[__][__][__][__]
Q8a	Elsewhere	1. Yes 2. No 88. Don't Know → **Q9**	C[__][__]
Q8b	8policy	Health policies are changed	[__] (all C)
	8learns	Learning about diseases - for sake of *all people* in the *future*	[__]
	8treats	Treat people/provide services in other places	[__]
	8aid	Assisting others (msaada, bus fare, food, nets etc)	[__]
	8DK	Don't know	[__]
	8Other	Other (specify)	[__]
	8spec	*Code for other: a) not asked/clear HOW; b) Has buildings/HQs/ found elsewhere; c) treats anyone who's sick/assists anyone; d) has heard from people; e) only talks about Kilifi; f) No response; g) For people to attain higher degrees; h) Many people go to KEMRI even from outside Kilifi; i) told by KEMRI staff members; j) seen them in other places; k) started elsewhere then came to Kilifi l) counting people/census*	[__][__][__][__]

Q9	9treats	Treating people at the time of illness/provides good health services/distributes drugs	[__](all C)
	9learns	Learning about diseases - for sake of *all people* in the *future*	[__]
	9drugs	**T**ests new drugs/ trials or **M**akes new drugs (T/M)	[__]
	9exp	Learns by experience… through practice gets to assist others	[__]
	9aid	Assisting the community (msaada, bus fare, food, nets etc bee hives)	[__]
	9teach	Teaching local community about health-related issues……	[__]
	9dk	Don't know/cannot rank /not ranked ……	[__]
	9other	Other (specify) ……	[__]
	9spec	*Code for other: a) collects info; DK why; b) teaching - other; c)? 9learns; unclear; d) ?9drugs; unclear; e)?9exp; unclear ; f) not clear if treats or aid; g) employment; h) HIV test/VCT; i) Census; j) Not clear; k) wants to prevent/eradicate malaria/diseases;*	[__][__][__][__]
QUESTION 10 – 15 OMITTED			
Q16	16treats	Makes decisions on the treatment of an individual patient ……..	[__](all C)
	16learns	Uses to learn about health and illness - *for the sake of all* not individ	[__]
	16exp	Learning by experience ……	[__]
	16stores	Stores to learn about health and illness *in the future* - *for the sake of all*	[__]
	16sells	Sells the blood ……	[__]
	16pools	Pools the blood for transfusions / **P**ositive (donation/help) / **S**ale	[__]-[__]
	16dk	Don't know……	[__]
	16other	Other (specify) ……	[__]
	16spec	Code for other: *a) those found positive/with probs get aid; b) not clear (?if research); c) stores blood, DK why*	[__][__][__][__]
Q 17-18 – OMITTED			
		SECTION 4	
Q19	Edn	Level reached: Standard, Form, Tertiary, Adult education - yys (99 missing; 88 dk; 00 none)	N[__][__]
Q 20 – 29 OMITTED			
Q30	support	1 Strongly supportive 2 Supportive 3 Indifferent 4 Unsupportive 5 Strongly unsupportive	N[__]
SECTION 5 OMITTED			
		SECTION 6	
Q33a	33fwhome	1. Yes 2. No 88. Don't know → **Q34a**	C[__][__]
Q33b	33fwvisit	Number of times fws visited in six months	N[__][__]
Q33c	33fwnos	Number of fws	N[__][__]
Q33d	33fwinfo	Collect info about family members/census	[__] (all Cs)
	33fwf-up	Followed-up for treatment/check health of child/follow-up in study	[__]
	33consent	Being asked to join study, consenting, ……	[__]
	33samples	Collecting samples/blood/nasal……	[__]
	33dk	……	[__][__]
	33other	Don't Know……	[__]
	33specify	Other (specify)……	[__][__][__][__]
		Specify a) collect information on resources/water sources/sanitation b) seeking directions to another place/home etc; c) collect information about studies/HIV etc.	
QN 34- 36 OMITTED			
		SECTION 7	
37a	37fwinfo	Agree (A), Neutral (N) Disagree (D)	C[__]
37b	37zaidi	Agree (A), Neutral (N) Disagree (D)	C[__]
37c	37fwtrue	Agree (A), Neutral (N) Disagree (D)	C[__]
37d	37fwgen	Agree (A), Neutral (N) Disagree (D)	C[__]
37e	37drcare	Agree (A), Neutral (N) Disagree (D)	C[__]
37f	37drdecn	Agree (A), Neutral (N) Disagree (D)	C[__]
37g	37drward	Agree (A), Neutral (N) Disagree (D)	C[__]

37h	37drtrust	Agree (A),	Neutral (N)	Disagree (D)	C[__]
37i	37benefit	Agree (A),	Neutral (N)	Disagree (D)	C[__]
EXTRA INFORMATION SECTION OMITTED					

Appendix L: Final coding schedule

1. **Information about the study**
   - 1.1. What the study is about
   - 1.2. Study size; participants (eligibility)
   - 1.3. Study procedures
   - 1.4. Benefits
   - 1.5. Stage of study and progress
   - 1.6. Engaging stakeholders
   - 1.7. h Study team members
     - 1.7.1. Different staff cadres
     - 1.7.2. 3 Coordination of study team

2. **FWs who they and their roles**
   - 2.1. 1 Categories of FWs
   - 2.2. 2 Roles of FWs
     - 2.2.1. At Recruitment and consent
     - 2.2.2. At study follow-up or data collection
     - 2.2.3. Others – mediate between KEMRI and community
   - 2.3. Change of FW roles, why and perceptions of the change
   - 2.4. How FWs are perceived by P others
     - 2.4.1. community views of FWs
     - 2.4.2. Study researchers expectations of FWs
   - 2.5. 5 Support systems for FWs (and study)
     - 2.5.1. 1 Formal systems (CAST, study team, involving researchers)
     - 2.5.2. 2 Peer support
     - 2.5.3. 3 Views on functioning of support system
   - 2.6. Expectations of FW roles
     - 2.6.1. By FWs
     - 2.6.2. By researchers
   - 2.7. FW perceptions of their roles
     - 2.7.1. Competence (skills and experience)
     - 2.7.2. Not respecting FWs
     - 2.7.3. FW chased away from home
     - 2.7.4. Not accepting other FWs

3. **Challenges that FWs faced in the studies**
   - 3.1. Amount of work
   - 3.2. about participants
     - 3.2.1. Uncooperative participants
     - 3.2.2. Reasons for refusals and withdrawals
     - 3.2.3. Participants vs non-participants in community
     - 3.2.4. Rumours in community
   - 3.3. About the study generally
     - 3.3.1. Study protocol
     - 3.3.2. Related to study procedures
     - 3.3.3. Related to study benefits (distribution) and expectations
     - 3.3.4. Related to logistics of the research
   - 3.4. How challenges were resolved
     - 3.4.1. Use of study benefits
     - 3.4.2. Use of support systems
     - 3.4.3. With participants
       - 3.4.3.1. About participants concerns
       - 3.4.3.2. About study benefits
       - 3.4.3.3. Familiarity with FWs and procedures
       - 3.4.3.4. Amongst Participants or community members
     - 3.4.4. about the study
       - 3.4.4.1. Study procedures

3.4.4.2. Incentives or additional benefits (compensations)

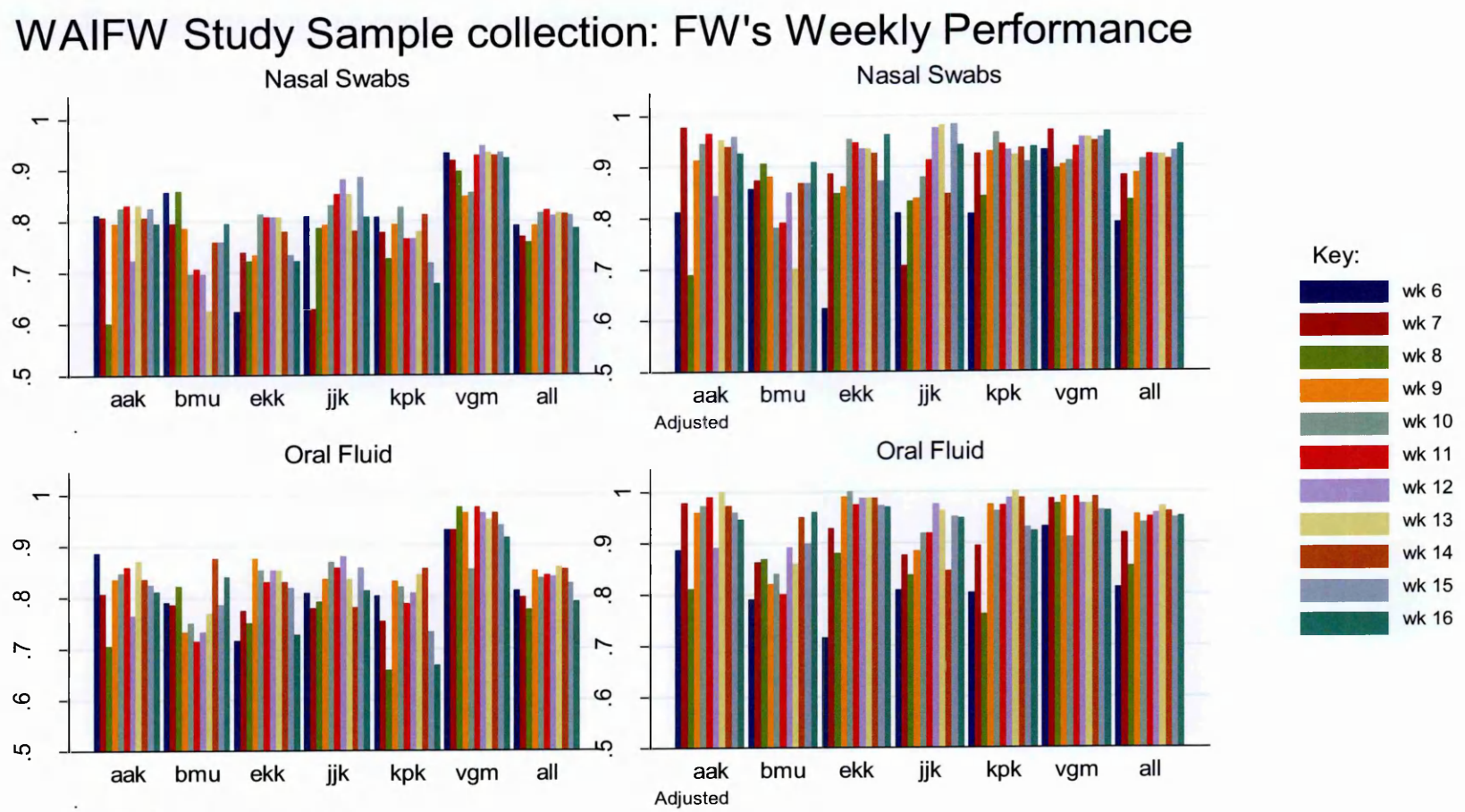
4. **4 Positive attributes about the study - what worked well**
   - 4.1. Study + community benefits
   - 4.2. Hard working and commitment by team members
   - 4.3. Interactions + relationships between Study team, FWs and rp
   - 4.4. Cooperative participants
   - 4.5. Keeping promises
   - 4.6. Meeting targets

5. **5 Recommendations**
   - 5.1. From FWs
   - 5.2. From researchers
     - 5.2.1. For Researcher
     - 5.2.2. On FWs
     - 5.2.3. On CAST
     - 5.2.4. Other studies

6. **Emerging themes**
   - 6.1. Household decision-making dynamics
   - 6.2. Study benefits in negotiations
   - 6.3. Social relations
   - 6.4. Silent refusal

7. **Issues about my position**

Appendix M: Performance chart for FWs in case study A

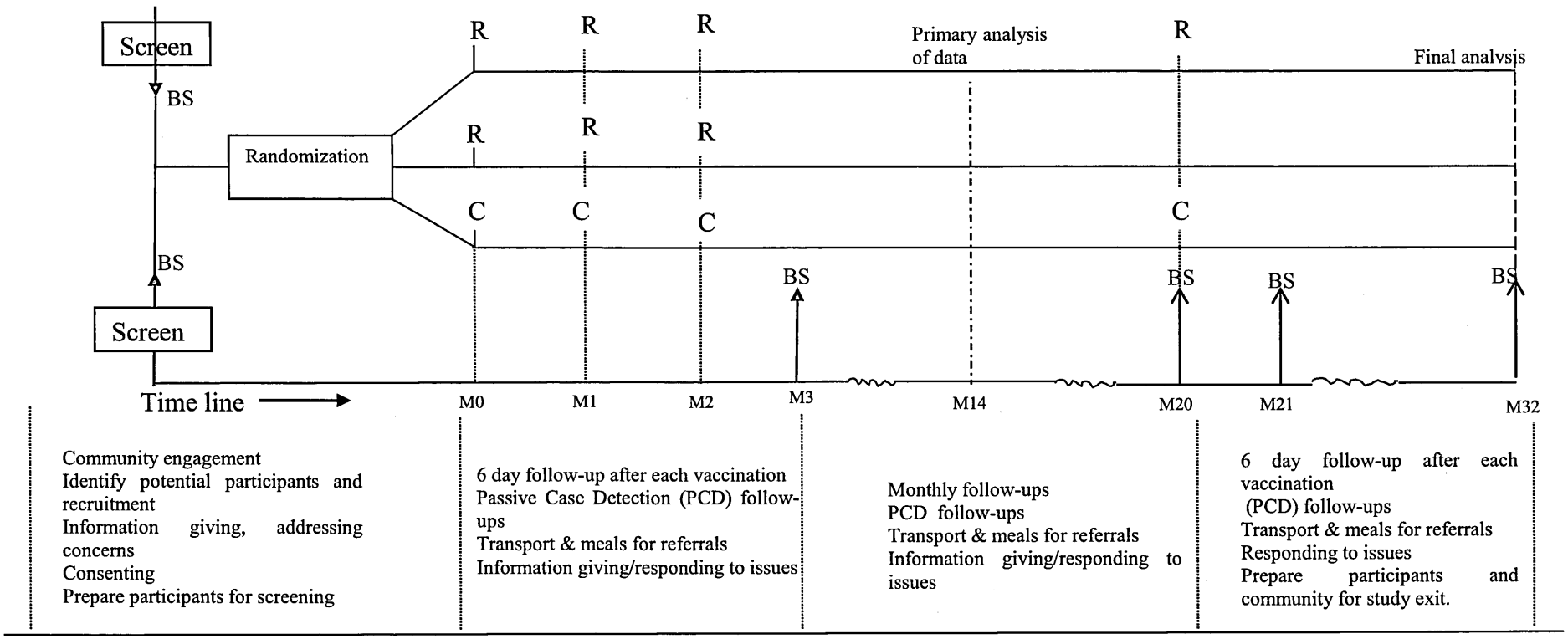


Source: WAIFW Study Checklists

79

[79] Abbreviations such as aak, bmu, ekk etc refer to individual fieldworker.

Appendix N: diagrammatic representation of case study B procedures



Legend

BS: Blood sample	R: Vaccination with RTS,S/AOIE vaccine
M: Study month	C: Vaccination with Control vaccine

Diagram Adapted from Supplement Figure 3.6 (Olotu, Lusingu et al. 2011 p36)